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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Docket No.: 99-DIV-17596B

Anticipated Classification of  
this application: Class \_\_\_\_\_

Prior Application:

Examiner: Troung, K.

Art Unit: 3309

**Assistant Commissioner for Patents  
Washington, D.C. 20231**

Sir: This is a request for filing a

☐ Continuation

☒ Divisional application under 37 CFR 1.63

of prior application Serial No. 08/598,804 filed on February 9, 1996,

of Phillip J. Snoke, Michael J. Mark, and David Scott Rowley,

for **STEERABLE CATHETER HAVING DISPOSABLE MODULE AND STERILIZABLE  
HANDLE AND METHOD OF CONNECTING SAME**

1. ☒ Enclosed is a copy of the prior application, including the oath or declaration as originally filed and an affidavit or declaration verifying it as a true copy.
2. ☐ Prepare a copy of the prior application.
3. ☒ The filing fee is calculated below:

**CLAIMS AS FILED IN THE PRIOR APPLICATION, LESS ANY CLAIMS CANCELED BY AMENDMENT BELOW:**

	(Col. 1)		(Col. 2)		SMALL ENTITY			LARGE ENTITY	
FOR:	# FILED		# EXTRA		RATE	FEE		RATE	FEE
BASIC FEE						\$ 395	OR		\$
TOTAL CLAIMS	14	-20	0	X	\$ 0	OR	X 18	\$ -	
INDEP CLAIMS	3	- 3	0	X	\$ 0	OR	X 78	\$ -	
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENTED						\$	OR		
* If the difference in Col. 1 is less than "0", enter "0" in Col. 2.					TOTAL	\$ 395		TOTAL	\$

jc520 U.S. PTO  
01/05/99

jc549 U.S. PTO  
09/225411  
01/05/99

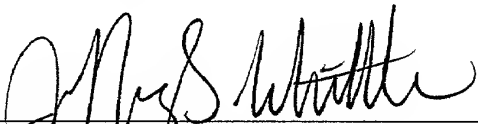
08/598,804

4. ☒ A check in the amount of **\$395** is enclosed to cover the filing fee. If any additional fees and/or fee for further claims is required, please charge Deposit Account No. **01-0484**.
5. ☒ Cancel in this application original claims **1-24 and 39-49** of the prior application before calculating the filing fee.
7. ☒ Amend the specification by inserting before the first line the sentence:  
--This application is a divisional of Serial No. 08/598,804 filed on February 9, 1996.
8. ☐ Transfer the drawings from the prior application to this application and abandon said prior application as of the filing date accorded this application. A duplicate copy of this sheet is enclosed for filing in the prior application file. (May only be used if signed by person authorized by Rule 138 and before payment of base issue fee.)
9. ☒ Formal drawings are enclosed.
- 9a. ☐ Priority of application Serial No. \_\_\_\_\_ filed on \_\_\_\_\_ in \_\_\_\_\_ is claimed under 35 U.S.C. 119. (country)
- 9b. ☐ The certified copy has been filed in prior application Serial No. \_\_\_\_\_ filed \_\_\_\_\_.
10. ☒ The prior application is assigned of record to **Catheter Imaging Systems, Inc., Atlanta, GA.**  
**Assignment recorded on April 10, 1996, on reel 7931/Frames 0100-0102.**
11. ☒ The power of attorney in the prior application is to:  
**Jeffrey S. Whittle, Reg. No. 36,382; Christopher F. Regan, Reg. No. 34,906; Herbert L. Allen, Reg. No. 25,322; Carl M. Napolitano, Reg. No. 37,405; and Jacqueline E. Hartt, Reg. No. 37,845, Allen, Dyer, Doppelt, Milbrath & Gilchrist, P.A., P.O. Box 3791, Orlando, FL 32801**  
(Name, registration number and address).
- a. ☐ The power appears in the original papers in the prior application.
- b. ☒ Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.
- c. ☒ Continue to address all future communications to:  
**Jeffrey S. Whittle, Reg. No. 36,382**  
**Allen, Dyer, Doppelt, Milbrath, Gilchrist, P.A.**  
**P.O. Box 3791, Orlando, FL 32802-3791**  
**(407) 841-2330**
12. ☒ Small entity status of this application under 37 CFR 1.19 and 1.27 has been established by a verified statement previously submitted in parent Serial No. 08.598,804 filed 02/09/96.
13. ☒ I hereby verify that the attached papers are a true copy of prior application Serial No. **08/598,804** as originally filed on **February 9, 1996**.

The undersigned declare(s) further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

January 5, 1999

Date



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- ☐ Inventor(s)
- ☐ Assignee of complete interest
- ☐ Filed under Rule 34(a)

(CIS17596B)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: )  
Phillip J. Snoke )  
Serial No. To Be Assigned ) Examiner: J. Yasko, Jr.  
Filed: Concurrent Herewith ) Art Group: 3734  
For: STEERABLE CATHETER HAVING )  
DISPOSABLE MODULE AND )  
STERILIZABLE HANDLE AND )  
METHOD OF CONNECTING SAME )  
\_\_\_\_\_)

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Please amend the above-identified application as follows:

IN THE CLAIMS:

Please cancel Claims 1-24 and 39-49.

In Claim 26, line 1, delete "31" and insert -25—  
therefor.

In Claim 27, line 1, delete "31" and insert -25—  
therefor.

In Claim 28, line 1, delete "31" and insert -25—  
therefor.

In Claim 29, line 1, delete "32" and insert -26—  
therefor.

In Claim 31, line 1, delete "36" and insert -30—  
therefor.

In Claim 32, line 1, delete "36" and insert -30—  
therefor.

In re Patent Application of:  
**Phillip Jack Snoke**  
Serial No. **To Be Assigned**

In Claim 33, line 1, delete "37" and insert -31-  
therefor.

In Claim 34, line 1, delete "37" and insert -33-  
therefor.

In Claim 35, line 1, delete "36" and insert -30-  
therefor.

**REMARKS**

It is believed that all of the claims are patentable over the prior art. Accordingly, after the Examiner completes a thorough examination and finds the claims patentable, a Notice of Allowance is respectfully requested in due course. Should the Examiner determine any minor informalities that need to be addressed, he is encouraged to contact the undersigned attorney at the telephone number below.

Respectfully submitted,



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Attorney for Applicant

cis:17596B

STEERABLE CATHETER HAVING DISPOSABLE MODULE AND  
STERILIZABLE HANDLE AND METHOD OF CONNECTING SAME

RELATED APPLICATIONS

This application is related to and a  
continuation-in-part of four pending design  
applications: Serial No. 29/046,932, filed November  
21, 1995 for *Steerable Catheter*; Serial No. 29/048,898  
5 filed January 12, 1996 for *Handle For Steerable*  
*Catheter*; Serial No. unassigned as of this filing date,  
Filed January 12, 1996 for *Steerable Catheter*; and  
Serial No. 29/048,899, filed January 12, 1996 for  
*Handle Interface For Steerable Catheter*.

FIELD OF INVENTION

This invention relates generally to medical  
catheters and more specifically to steerable catheters  
for inserting into vessels, cavities, or tissue of the  
human body.

BACKGROUND OF THE INVENTION

Various commercially available endoscopes and  
steerable catheters exist for introducing a variety of  
surgical tools, fluids, and other materials such as  
radiographic contrast materials, angioplasty balloons,  
20 fiber optic scopes, laser lights, and cutting  
instruments into the vessels, cavities, or tissue of a  
human body. Also, various techniques and systems have  
been developed for guiding or steering the catheters or  
endoscopes in body vessels or cavities for use with  
25 these tools, fluids, and other materials. Therapeutic

or diagnostic treatments may be made by inserting surgical instruments or fluid through a working channel or lumen of a catheter.

Catheters conventionally include a conduit or flexible tube for inserting into a cavity, duct, or vessel of the human body to allow fluids to pass therethrough or to allow instruments to be inserted through the tube. Catheters also have been developed with steering mechanisms to guide or manipulate the catheter such as seen in U.S. Patent No. 5,199,950 by Schmitt et al. titled "*Medical Instrument.*" Endoscopes are generally tools used to view within a portion of the anatomy through an open end of a tube. Flexible endoscopes have been constructed for use within "tube-like" portions or cavities of the anatomy (e.g., arteries, ureters, common bile duct). Endoscopes have been designed for the user to look directly through an objective lens or in conjunction with video cameras attached remotely to the scope for viewing a portion of the human body. Rod lens systems also have been used with some endoscopes to view images. In other endoscopes, the image is gathered at the distal end by a lens and transferred to a proximal objective lens using fiber optic bundles.

During use in medical procedures, endoscopes and steerable catheters are exposed to various viruses, bacteria, and harmful disease carrying media. These viruses and bacteria can be trapped in the endoscope or steerable catheter, particularly in lumens and transferred to subsequent patients or users. During use of these medical devices, microbes have also been trapped inside patient materials that remain in the endoscopes and become coated with lubricants and various organic materials in the endoscope. If not effectively eliminated, these materials can and have been transferred to other patients or medical personnel through subsequent use of the endoscope or steerable

catheter. In the human body, enzymes and digestive processes work to release these internally trapped microbes from the lubricant coatings. These harmful microbes can infect the subsequent patients or medical personnel with dangerous or deadly diseases.

Sterilization methods have been employed on reusable medical devices, including various endoscopes and steerable catheters, in an attempt to disinfect and eliminate viruses and bacteria for subsequent use of the devices. For example, glutaraldehyde has been used to treat reusable endoscopes. Also, heat sterilization and other chemical disinfection have been employed to attempt to sterilize internally contaminated medical devices. Some endoscopes and steerable catheters contain very small and narrow working channels or lumens for performing intricate medical procedures. These small or narrow working channels or lumens are difficult to clean and sterilize. Further, research has shown that, in spite of attempts to sterilize endoscopes, endoscope lubricants can shield viruses, including HIV, from high-level disinfection. Disease transmissions have been documented for endoscopes used in diagnostic and surgical procedures even after treatment with chemicals such as glutaraldehyde. The instances of epidemics of various diseases, including new and old diseases, are rising due to the increasing density of human population and frequency of human contact. At the same time, the effectiveness of certain antibiotics is diminishing and the numbers of individuals with increased susceptibility to disease is on the increase. Technological advances have also increased the frequency of use of medical instruments which are difficult to clean, yet are not disposable. These factors have produced an environment where the likelihood of infection caused by passing disease causing viruses, bacteria, or other matter is rapidly increasing.



In addition to the problem of infection and transmission of disease, prior endoscopes and catheters by virtue of their design and materials have been intended for prolonged, repeated use. The precision of manipulation and movement in endoscopes and steerable catheters is essential for conducting the complicated medical procedures and diagnostics generally employed by such devices. Some repeated use endoscopes and steerable catheters have contained steering mechanisms to manipulate the endoscopes within the human body. These mechanisms have been complicated and required precision calibration. Further, these devices have also had to withstand sterilization with heat or chemicals. To accomplish these objectives, reusable endoscopes and steerable catheters have been made of steel or other durable metals which are costly.

To maintain integrity and precision, endoscopes and steerable catheters have generally been designed as intended for repeated, prolonged use. In spite of being designed for repeated use, however, these scopes such as laparoscopes, require replacement much more frequently than other visualization equipment such as cameras or light sources. A typical replacement cycle is one to two years. In high volume surgery centers, some scopes require replacement after a few weeks or months due to damage from mishandling or dropping. Repairing these endoscopes is also costly. The requirement of sterilization also adds additional cost to each medical procedure requiring additional chemicals and equipment.

Limited attempts have been made to provide a detachable reusable endoscope. One repeated use detachable-end endoscope with a detachable flexible shaft is described in U.S. Patent No. 4,911,148 by Sosnowski et al. titled "Deflectable-End Endoscope With Detachable Flexible Shaft." This patent describes a flexible shaft assembly which connects to a handle

subassembly to form an endoscope. The handle subassembly includes a hollow female bayonet connector which couples with a male connector in the shaft subassembly. The endoscope described in U.S. Patent No. 4,911,148 by Sosnowski has a central opening extending from a proximal end to the distal end of the endoscope. A lens is positioned within the opening to provide appropriate magnification for an operator to manually view the distal end of the endoscope. This endoscope is also intended for reuse as both the shaft subassembly and handle subassembly are provided with watertight seals to prevent a compromise of internal components resulting from usage and sterilizations. The shaft subassembly, however, as described above, has some of the sterilization failures of previous technology and provides an awkward and inefficient manner for viewing the distal end of the endoscope.

In addition to the issues of disease transmission and disposability, numerous endoscopes have been designed which are bulky or difficult to use, requiring numerous hands or personnel. Hand-held catheters have been developed to provide the control and manipulation of the catheter for simultaneous use with surgical tools, fiber optic scopes, and fluids needed for medical operations, such as in United States Patent No. 5,342,299 by Snoke et al. titled "*Steerable Catheter*." Many medical procedures, however, require passage of relatively straight instruments into the human body at an angle difficult to actuate relative to the position of the portion of the medical device in the medical practitioner's hand.

As stated, none of the prior catheter or endoscope systems utilized fiber optic imaging systems to view within a human body. These systems required the use of an endoscope or catheter in conjunction with an external camera for transmitting images from within a human body to an external monitor. These external

cameras occupied limited space in the operating or examination rooms and were susceptible to breakage or contamination. Still further, these cameras needed to be designed to withstand required direct sterilization.

5           Charged-coupled devices ("CCD's") have been proposed for use with endoscopes allowing direct image capture at the distal tip of an endoscope. Such systems conventionally place a camera chip at the distal end of a scope such as a laparoscope are referred to as a "chip-on-a-stick." These chip-on-a-stick devices are used in conjunction with an external camera connected to the scope by a cable. These chip-on-a-stick devices have several problems associated with them. For example, the scope may become contaminated during a procedure and sterilization often cannot be adequately performed on the device because of the presence of the CCD chip. This CCD chip also makes the scope somewhat expensive, especially where contamination occurs and sterilization is not possible without damaging the chip.

10           In chip-on-a-stick systems, the chip-on-a-stick generally would not be susceptible to sterilization at the tip of the endoscope because the camera chip is positioned on or around the tip. These external cameras also require space in shipping and storage. Prior endoscopes or steerable catheters which utilized fiber optic technology also often had an external focus mechanism associated with the external camera. This would require the practitioner to look or reach away from the area of the procedure to focus the image being viewed within the human body.

#### SUMMARY OF THE INVENTION

15           The present invention solves the aforementioned problems by providing a steerable catheter and methods including a reusable handle having a body and control means detachably connected to the interface of a disposable module which has an elongate

tube including at least one lumen and deflecting means to provide a steerable catheter having a disposable module and a sterilizable handle for inserting at least portions thereof into a vessel, cavity, or tissue of a human body to thereby provide manipulation of a distal portion of the catheter when positioned within a vessel, cavity, or tissue. The present invention advantageously provides a steerable catheter having a disposable module and a sterilizable handle to eliminate or reduce the problem of disease transmission by providing a detachable steerable catheter including a disposable module designed for a single use which contains the difficult to sterilize working channels or lumens which can be utilized in conjunction with a reusable handle which can be effectively sterilized after each use. A detachable steerable catheter preferably includes a module having an elongate tube which is disposable after each use.

The present invention also advantageously provides a detachable steerable catheter having a module including an elongate tube having at least one lumen within the tube with the module being easily detachably connected to a reusable handle which can be repeatedly sterilized to provide a cost-effective medical device which greatly reduces the possibility of transmission of disease from repeated use of the device. The present invention further advantageously provides a cost-effective disposable steerable catheter which retains the integrity and accuracy required during surgical uses. By providing a steerable catheter having a disposable module and a sterilizable handle the cost-per-procedure is reduced, and a reusable, easily sterilized handle according to the present invention retains the necessary precision which instills confidence in the medical practitioner due to its construction and ergonomic characteristics.

In accordance with the present invention, a steerable catheter having a disposable module and a sterilizable handle is provide for use in human body vessels, cavities, or tissue. The detachable steerable catheter preferably includes a module including an elongate tube having at least one lumen extending from a distal end to a proximal end of said tube, a module interface connected to the proximal end of said tube, and deflecting means connected to said tube for deflecting the distal portion of said elongate tube. The detachable steerable catheter further has a handle detachably connected to the module and configured to be readily held in the hand of a user. The handle preferably includes a body having a wall positioned in distal portions of the body. The wall has an outer surface defining an exterior portion of the body. The handle also has a first cavity formed within the body. The body is detachably and coextensively connected to the module interface through the outer surface of the wall. The handle also includes control means connected to the body and detachably connected to said deflecting means of the module for responsively controlling the deflecting means to thereby manipulate distal portions of the elongate tube. The control means and the deflecting means are connected to define a unitary catheter manipulation means which extends from the first cavity, through the wall, and to the tube for manipulating a distal portion of the catheter when positioned within a vessel, cavity, or tissue.

This steerable catheter having a disposable module and a sterilizable handle is for inserting at least portions thereof into a vessel, cavity, or tissue of a human body to thereby provide manipulation of a distal portion of the catheter when positioned within a vessel, cavity, or tissue. In an illustrative embodiment, the outer surface of the wall and a lower surface of the module interface also detachably connect

to define a second cavity. The control means and the deflecting means are detachably connected within the second cavity so that the unitary catheter manipulation means extends from the first cavity, through the wall, through the second cavity, and to the tube for manipulating a distal portion of the catheter when positioned within a vessel, cavity, or tissue.

The present invention also includes methods of connecting and using a catheter. A method of detachably connecting a catheter having a handle which includes a body and a detachable module which includes an elongate tube having at least one lumen extending therethrough is provided by the present invention. This method preferably includes connecting a fiberscope to a distal end portion of the body of the handle, positioning the fiberscope into the at least one lumen of the tube of the module, and connecting the module to the body of the handle for viewing portions of a vessel, cavity, or tissue when a distal end of the tube is positioned therein.

The catheter and methods of the present invention further provide a detachable catheter with a reusable fiber optic scope which can be detachably connected to the handle and sealed within the detachable module during a medical procedure. A steerable catheter having a disposable module and a sterilizable handle according to the present invention also can advantageously be provided in a kit which, for example, includes a plurality of detachable, disposable modules and a reusable handle and fiber optic scope to be used with the disposable modules. The handle of a steerable catheter having a disposable module and a sterilizable handle according to the present invention can further include an angled handle that provides entry to positions of the human body while allowing the medical practitioner to grasp the steerable catheter in an advantageous hand position. A detachable steerable

catheter can also advantageously include a camera mounted internally in the handle of the catheter wherein the handle can be sterilized with the camera therein, and the camera is protected from breakage or contamination therein. A steerable catheter and methods according to the present invention further can provide a steerable catheter having a focus means positioned on the handle of the catheter for focusing the internal camera positioned within the handle. A steerable catheter and methods of the present invention also advantageously provide a disposable module and a sterilizable handle having a focus wheel and control wheel disposed such that the focus wheel and control wheel can be simultaneously adjusted by the same hand of the practitioner.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Some of the objects and advantages of the present invention having been stated, others will become apparent as the description proceeds when taken in conjunction with the accompanying drawings as follows:

Figure 1 illustrates an environmental view of a medical procedure being conducted on a patient using a steerable catheter having a disposable module and a sterilizable handle according to the present invention positioned within an opening in the urological region of a human body by a medical practitioner for a therapeutic treatment of a problem area;

Figure 2 illustrates an environmental perspective view of a steerable catheter having a disposable module and a sterilizable handle being held by the hand of a medical practitioner while simultaneously controlling an imaging system and manipulating a distal end portion of the catheter according to an embodiment of the present invention;

Figure 3A illustrates a perspective view of a steerable catheter having a disposable module and a

sterilizable handle according to the present invention showing a fiber optic scope being detachably connected to the handle;

5 Figure 3B illustrates a perspective view of a steerable catheter having a disposable module and a sterilizable handle according to the present invention showing the fiber optic scope detachably connected to the handle and the module being positioned to slide over the fiber optic scope to detachably connect to the handle;

10 Figure 3C illustrates a steerable catheter having a disposable module and a sterilizable handle according to the present invention having a detachable connected fiber optic scope positioned within the module and having the module positioned to detachably connect to the handle;

15 Figure 3D illustrates an exploded perspective view of an imaging interface including an imaging capture device and a fiber optic scope of a steerable catheter according to the present invention;

20 Figure 4 illustrates an enlarged perspective sectional view of a steerable catheter having a disposable module and a sterilizable handle according to the present invention showing a module interface of the module having medical instruments inserted within a lumen of the module;

25 Figure 5 illustrates a cross-sectional view taken along line 5-5 of Figure 3B showing a module of a steerable catheter detached from a handle according to an embodiment of the present invention;

30 Figure 6 illustrates a cross-sectional view taken along line 6-6 of Figure 3B showing a handle with a detachably connected fiber optic scope of a detachable steerable catheter according to the present invention having an imaging cable detachably connected to the handle;

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Figure 7 illustrates a side view taken according to line 7-7 of Figure 3C showing an embodiment of a steerable catheter according to the present invention having a module and a fiber scope detachably connected to a handle with the fiber scope positioned within the module and having a medical instrument inserted within an access port and working lumen of the catheter;

Figure 8 illustrates a top view taken along line 8-8 of Figure 7 of a steerable catheter having a disposable module and a sterilizable handle according to the present invention showing a controller means detachably connected to a deflector of the module;

Figure 9 illustrates a top view taken along line 9-9 of Figure 7 showing an imaging interface cable and a focus cable connected to a shaft of a focus wheel and a focus controller disposed within a handle of a detachable steerable catheter according to the present invention;

Figure 10 illustrates a side view taken along line 10-10 of Figure 8 showing a steerable catheter having a disposable module and a sterilizable handle according to the present invention including an imaging system disposed within the handle;

Figure 11 illustrates an enlarged cross sectional view taken along line 11-11 of Figure 3C illustrating working lumens, a fiber optic scope lumen, deflecting wires, and an outer circumference of an elongate tube of a catheter according to the present invention;

Figure 12 illustrates an enlarged fragmentary view of a distal portion of a catheter according to the present invention illustrating the insertion of deflecting wires within the catheter and showing a top of an elongate tube in phantom view;

Figure 13 illustrates a sealed disposable module of a detachable steerable catheter according to the present invention for use in a kit; and

Figure 14 illustrates a steerable catheter having a disposable module and a sterilizable handle forming a kit according to the present invention including an individually packaged handle, fiber scope, and a plurality of modules within a single secondary package for distribution.

#### DETAILED DESCRIPTION

The present invention now will be described more fully hereinafter with reference to the accompanying drawings in which preferred embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the illustrated embodiments set forth herein; rather, these illustrated embodiments are provided so that this disclosure will be thorough and complete and will fully convey the scope of the invention to those skilled in the art. Like numbers refer to like elements throughout.

With further reference to the drawings, Figure 1 illustrates an environmental view of a disposable steerable catheter 20 according to the present invention being used by a medical practitioner or doctor D in a medical procedure on a human body B. This embodiment of a disposable steerable catheter 20 is for inserting at least portions thereof into a vessel, cavity, or tissue of the human body B to thereby provide manipulation of a distal portion of the catheter 20 therein and to perform medical procedures using this catheter 20. The detachable and disposable steerable catheter 20 enables the medical practitioner D to insert medical instruments and fluids into a human body B and to view images from therein. Medical, surgical, and diagnostic procedures can be performed using a steerable catheter 20 having a disposable

module 50 and a sterilizable handle 30 according to the present invention. Particularly, Figure 1 shows the insertion of a detachable steerable catheter 20 according to the present invention into the urological canal during surgery. Procedures in other regions of the body could also effectively utilize the steerable catheter 20 having a disposable module 50 and a sterilizable handle 30 according to the present invention including procedures in the epidural region, the sinus cavity and/or nose region, the brain region, and other regions of the human body B.

As illustrated in Figures 3A-3D, the detachable steerable catheter 20 according to the present invention has a handle 30 detachably connected to a module 50. At least a distal portion 30a of the handle 30, and preferably the distal portion 30a and a bulbous portion 30b, has a bulbous shape. The handle 30 also is preferably configured to be readily held in the hand H of a user as shown in Figure 2. More specifically, the detachable steerable catheter 20 has a module 50 including an elongate tube 55 having at least one lumen 67, 68, 69 (Figure 12) preferably extending from a distal end portion 58 to a proximal portion 56 of the tube 55 as best shown in Figures 3B and 12. The module 50 also includes a module interface 53 connected to the proximal portion 56 of the tube 55 and deflecting means, e.g., deflector 60, associated with and preferably connected to the tube 55 for deflecting the distal end portion 58 of the elongate tube 55 as shown in Figures 5, 11, and 12. The deflecting means 60 preferably includes a pair of steering wires 61, 62 positioned within and coaxially extending the substantial length of the tube 55. It will be understood by those skilled in the art, however, that other types of deflectors 60 may be used as well.

The handle 30 has a body 31 including a wall 32 positioned in distal portions of the body 31 as shown in Figure 3A. The wall 32 has an outer surface 32a defining an exterior portion of the body 31 without the module 50 connected thereto. The body 31 further includes a first cavity 34 positioned within the body 31 as shown in Figure 6. The body 31 preferably is detachably and coextensively connected to the module interface 53 through the outer surface 32a of the wall 32.

The handle 30 also has control means, e.g., controller 40, connected to the body 31 and detachably connected to deflecting means 60 of the module 50 as shown in Figures 7-10. The control means 40 is positioned to responsively control the deflecting means 60 to thereby manipulate distal end portions 58 of the elongate tube 55. The control means 40 and deflecting means 60 are connected to define a unitary catheter manipulation means, e.g., manipulator 80, extending from the first cavity 34 through the wall 32 into the tube 55 for manipulating a distal end portion 58 of the catheter 20 when positioned within a vessel, cavity, or tissue of the human body B.

Figure 7 illustrates an embodiment of a steerable catheter 20 having a disposable module 50 and a sterilizable handle 30 according to the present invention wherein the outer surface 32a of the wall 32 of the body 31 and a lower inner surface 53a of the module interface 53 come together to form a second cavity 38. The control means 40 and deflecting means 60 are detachably connected within the second cavity 38 and to the tube 55 as shown in Figure 7. The unitary catheter manipulation means 80 extends from the first cavity 34 through the wall 32 and through the second cavity 38 into the tube 55 for manipulating a distal end portion 58 of a catheter 20 when positioned within a vessel, cavity, or tissue.

As best illustrated in Figures 3A, 3B, and 3D, a fiber optic scope 90 is also connected to an imaging interface 25 of an imaging system 24 positioned in the body 31 of the handle 30. The imaging interface 25 is preferably positioned within the second cavity 38 as shown in Figure 10. The fiber optic scope 90 preferably is a fiber optic scope 90 used to transmit light from an external light source to within the human body B to illuminate a vessel, cavity, or tissue as well as to receive images captured within the human body B. The fiber optic scope 90 provided according to the present invention preferably is reusable and able to be repeatedly sterilized. Upon connection of the module 50 and handle 30, the second cavity 38 preferably is sealed by the connection of the peripheral edge portions 51 of the module 50 and the edge portions 37 of the handle 30. The connection of the fiber optic scope 90 to the imaging interface is thus protected within this second cavity 38.

The handle 30 is also provided to be sterilized and used repeatedly. The body 31 of the handle 30 preferably is constructed of a suitable material which can withstand heat sterilization temperatures and chemical sterilization as understood by those skilled in the art. These sterilization methods are understood by those skilled in the art and, therefore, will not be discussed further. The handle 30 is also constructed of a material which possesses structural properties which allow for repeated detachable connection to a plurality of modules 50. Further, the material of the handle 30 facilitates the ergonomic advantages of the handle 30 such that the handle 30 is light weight and able to be configured to be readily held in the hand H of a user. The handle 30 preferably is sealed along its exterior openings by seals such as o-rings 39 as shown in Figure 6 to protect the first cavity 34.

The module 50 preferably is intended to be disposed of after a single use. The module 50, including the module interface 53, is also constructed of a material which possesses structural properties which allow for detachably connecting the module 50 to the handle 30. Further, the module 50 is constructed of a material which is lightweight and allows for manipulation and deflection of the elongate tube 55 within the body 31. Also, the module 50 in its intended single-use capacity is also provided of a material which can be cost effectively disposed of after a single use. As such, the elongate tube 55 is preferably constructed of suitable materials such as a thermoset or a thermoplastic. The module interface 53 also is constructed of suitable materials such as a thermoset or a thermoplastic. Although the handle 30 and fiber optic scope 20 are preferably reusable, a detachable steerable catheter 20 according to the present invention having a disposable handle 30 or fiber optic scope 90 could be provided within the context of the present invention.

Further, the embodiment of Figure 2 is shown having a plurality of access ports 64, 65, 66 for inserting fluids or medical instruments within a catheter 20 and into a cavity, vessel, or tissue of the human body. By way of example, Figure 3C illustrates a tube 55 connected within an access port 64 for introducing fluids into the human body B. Figure 1 illustrates a medical instrument I being inserted through one of a plurality of access ports 64, 65, 66 of the steerable catheter 20 having a disposable module 50 and a sterilizable handle 30 according to the present invention. Further, for example, the elongate tube 55 can also be provided to include at least one lumen 67, 68 which extends from the proximal portion 56 toward the distal end portion 58 of the tube 55 as shown in Figures 5 and 12, but stops short of the end

of the distal tip 59 of the tube 55. This lumen 67, 68 can be utilized for supplying an air supply for inflating a balloon for various procedures. The elongate tube 55 can be sized having various outer diameters, a plurality of lumens, and lumens having various diameters and shapes.

The diameter of the elongate tube 55 depends on the end application of the detachable steerable catheter 20. In diagnostic visualization and fluid delivery applications, for example, a catheter 20 having an elongate tube 55 having an outer diameter of about 2mm is preferable. With inserting instruments, suction, irrigation, or procedures utilizing balloons such as angioplasty, for example, an elongate tube 55 having an outer diameter of about 3 to 3.5 mm is preferable. In applications related to urology, for example, an outer diameter of about 2.5 to 3 mm is preferable for the elongate tube 55 of the detachable steerable catheter 20 according to the present invention. The module 50 can also have different durometers and different port functions. As such the detachable steerable catheter 20 according to the present invention is designed to facilitate ease of use in a single hand-held unit.

Figures 3A-3D illustrate a series of perspective views of a steerable catheter 20 having a disposable module 50 and a sterilizable handle 30 according to the present invention as well as of a method of detachably connecting this catheter 20. The detachable steerable catheter 20 is preferably detachably connected as follows. First, a sterilized handle 30 and a sterilized fiber optic scope 90 as described above are provided. The handle 30 includes an imaging interface 25 which is preferably connected within the body 31 of the handle 30 such that it extends from within the first cavity 34 of the body 31 through the wall 32 of the body 31 as illustrated in

Figure 3A and Figure 6. Preferably, the imaging interface 25 includes a female bayonet connector 26 including opposite grooves 27a, 27b (not shown) for detachably connecting the imaging interface 25 to the proximal end 92 of the fiber optic scope 90. The fiber optic scope 90 includes a male bayonet connector 94 connected to the proximal portion of the fiber optic scope 90. The imaging interface 25 and fiber optic scope 90 connect in a male/female bayonet connection as shown in Figure 6. The fiber optic scope 90 includes flanges 95a, 95b extending outwardly from opposite sides of the proximal female connector 26 which mate with the grooves 27a, 27b in the image interface 25 to perform the bayonet connection. Various other connectors could also be used as understood by those skilled in the art. The fiber optic scope 90 is detachably connected by sliding the fiber optic scope 90 longitudinally onto the imaging interface 25 as shown in Figures 3A and 3D. Other equivalent connections could be provided which would allow for the fiber optic scope 90 to be easily detachably connected. This connection provided, in the preferred embodiment, provides a connection between the imaging bundle and the light source of the imaging interface 25 which interacts with the fiber optics of the fiber optic scope 90.

With the fiber optic scope 90 detachably connected to the handle 30, a disposable module 50 as illustrated in Figure 3B and described above is also provided. The distal end 93 of the fiber optic scope 90 is preferably coaxially aligned with a lumen 69 in the proximal end of the module 50 as shown in Figure 3B. The lumen 69 extends from the module interface 53 through the elongate tube 55 to the distal end 59 of the elongate tube 55. The fiber optic scope 90 is slid longitudinally coaxially within the lumen 69 toward the distal portion 58 of the elongate tube 55. The fiber



optic scope 90 is sized to extend longitudinally coaxially through the elongate tube 55 from the proximal portion 56 to the distal end portion 58 of the elongate tube 55 within this lumen 69. Figure 3B shows the module 50 receiving the fiber optic scope 90 within the scope lumen 69 of the module interface 53.

Sliding the module 50 over the fiber optic scope 90 will generally align the module 50 and handle 30 to facilitate detachably connecting them. The module interface 53 and body 31 of the handle 30 are then detachably connected via connection means, e.g., connectors or mating peripheral edges 37, 51. For example, the connecting means could also include ribs and grooves located reciprocally on the module interface 53 and body 31. The module 50 may likewise have ribs on the upper proximal portion and a lower proximal portion. These ribs may detachably connect to grooves connected in the medial portion of the body 31 on an upper surface and on the distal portion on a lower surface of the body 31 with the module connecting means and body connecting means with one comprising ribs and the other comprising grooves whereby the ribs and grooves connect to detachably connect the module 50 to the body 31 of the handle 30. As understood by those skilled in the art, other connecting means could also be used, such as snap fitting connectors. The connecting means could also be located in other portions of the module 50 or handle 30.

The module 50 and handle 30 are connected to provide various structural advantages as described below. Connecting the module interface 53 to the body 31 of the handle 30 preferably will positionally locate or align the controlling means 40 of the handle 30 and the deflecting means 60 of the module 50 for detachably coupling them. The control means 40 and the deflecting means 60 will be detachably connected utilizing a tap engager 75 located on the module 50 as best illustrated

in Figures 3C and 5. Figures 3B, 3C, 5, and 6 show the steps of detachably connecting the module 50 to the handle 30 and coupling the control means 40 of the handle 30 to the deflecting means 60 of the module 50 to actuate manipulation of the elongate tube 55.

An imaging cable 89 preferably is then detachably connected into an image port 36 positioned in the proximal end 30b of the handle 30 as illustrated in Figure 6. Although conventional male/female connectors preferably are utilized, other connectors also could be utilized. The steerable catheter 20 having a disposable module 50 and sterilizable handle 30 is thus detachably connected for use in the intended medical procedure. Once detachably connected, the detachable steerable catheter 20 according to the present invention provides the medical practitioner with the ability to deflect or manipulate the distal end portions 58 of the tube 55 within a human body B. The detachable steerable catheter 20 also provides the practitioner D with the ability to focus images from within the human body B using focus means 100 connected to the body 31 of the handle 30 of the catheter 20. Further, the medical practitioner D can also insert fluids or medical instruments I into the human body B using this catheter 20.

Upon completion of the medical procedure, the steerable catheter 20 having a disposable module 50 and a sterilizable handle 30 according to the present invention can be easily disconnected. In the preferred embodiment, the tap engager 75 is provided with a detachment knob 78 as shown in Figure 5. The detachment knob 78 preferably is grasped and activated by pulling, thereby breaking a connection within the module 50 which allows the module 50 to detach from the handle 30. The handle 30 remains equipped to be repeatedly sterilized and receive another sterilized disposable module 50. The module 50 is slidably

removed from the fiber optic scope 90 and disposed. The fiber optic scope 90 can then be disconnected in this embodiment by rotating the bayonet connection and sliding the fiber optic scope 90 off the imaging interface 25. The module 50 is preferably discarded, while the fiber optic scope 90 and handle 30 are preferably sterilized for reuse. The imaging cable 89 can be disconnected by unplugging from the port 36.

The detachable connection between the handle 30 and the module 50 provides structural advantages over prior steerable catheters. For example, in the embodiment of the detachable steerable catheter 20 as illustrated in Figure 1, the elongate tube 55 will not rotate relative to the handle 30 during manipulation of the tube 55 within a human body B. Figure 7 shows the detachable steerable catheter 20 where the body 31 of the handle 30 has body connecting means, e.g., peripheral edge 37, connected to a medial portion on one surface and a distal portion on an opposite side of the body 31 for detachably connecting to the module interface 53. The module interface 53 includes interface connecting means, e.g., peripheral edge 51, connected to the proximal portion of the module 50 for detachably connecting to the body 31. In Figure 7, the connecting means is detachably connected to the body connecting means in medial and distal portions of the body 31 such that the body 31 and the module interface 53 define a unitary structure having sufficient stability such that the module 50 remains connected to the handle 30 and the tube 55 does not rotate relative to the handle 30 when the tube 55 is manipulated within the human body B. This stability of the connection is provided by the design of the module 50 and handle 30.

The module connecting means 51 detachably connects to the body connecting means in the medial portion 30c of the body 31 of the handle 30. The proximal portion of the module interface 53

coextensively overlies the body 31 from the distal portion 30a of the body 31 to the medial portion 30c of the body 31 such that the module 50 remains connected to the handle 30 and the tube 55 does not rotate relative to the handle 31 during manipulation of the tube 55 within the human body B as shown in Figures 5 through 7. This embodiment has an upper proximal portion of the module 50 overlying the body 31 of the handle 30 to detachably connect at the medial portion of the upper surface of the handle 30 as shown in Figures 5 to 7. Other embodiments, however, could be provided with a module 50 extending in a lower or side portion to overlie the body 31 to provide similar structural stability when the tube 55 is manipulated in the human body B. The tube 55 can be rotated 360° about the longitudinal axis defined by the tube 55 by the practitioner rotating the handle 30. As such, the tube 55 can contact the body 31 in various angles and directions further requiring a secure and stable connection. This connection gives the advantage of having the module 50 extend to the medial portion 30c of the body 31 providing stability for the connection. When the tube 55 is manipulated within the body 31, torque can be transferred from the tube 55 to the handle 30.

The shape of the detachable steerable catheter 20 having an elongate tube 55 and handle 30 concentrates stress at the point where the tube 55 and handle 30 connect. For example, the tube 55 could break off or crack if the two components, the module 50 and handle 30, were not securely connected. Further, if the connection were not strong enough, the force and torque caused by manipulation would break the connection such as if the tube 55 was connected to a small portion of the distal end 30a of the handle 30. The connection described also contains many other

structural advantages and advantages of ease of use, e.g., ready and ease of assembly.

Further, the module interface 53 preferably has non-uniform proximal edge portions 51 as illustrated which define the proximal end 53a of the module 50 as shown in Figures 3B and 3C. The body 31 of the handle 30 preferably has non-uniform edge portions 37 and a wall 32 which preferably transversely extends across the handle body 31. The non-uniform proximal edge portions 37 of the module interface 53 detachably connect to and mate with the non-uniform edge portions of the wall 32 and body 31 of the handle 30 to define a non-uniform continuous boundary between the module 50 and the handle 30 whereby the module 50 is stabilized relative to the handle 30 during manipulation of the tube 55 within a human body as shown in Figures 3A-C and Figure 2.

For added stability, the module 50 as illustrated in Figures 2 and 3C also extends in its upper proximal portion in a lateral direction across the body 31 of the handle 30. The lateral portion extends at a width greater than the width of the elongate tube 55 such that the module 50 remains connected to the handle 30 and the tube 55 does not rotate relative to the handle 30 during manipulation of the tube within the human body. The tube can be rotated laterally in a single plane by the deflecting means 60 connected within the elongate tube 55. The entire handle 30 can also be rotated with the tube 55 deflected to rotate in a 360° plane, but for added stability may also only be deflected in a 180° plane. During this movement, stability is needed in the connection between the module 50 and the handle 30.

As described above, in reference to Figure 2, the detachable steerable catheter 20 according to the present invention further has controlling means 40 for controlling portions of the tube 55 within a cavity,

vessel, or tissue of a human body. The control means  
40 preferably includes a control wheel 41 which can be  
rotated to activate control connector means for  
controlling the deflecting means 40 to manipulate the  
portions of the tube 55 within a human body B. The  
body 31 preferably has a recessed portion 23 formed in  
the outer surface as shown in Figure 3A. The control  
wheel 41 preferably is connected in this recessed  
portion 23 for ease of handling and control. As shown  
in Figure 6, the control wheel 41 is substantially  
positioned within this recessed portion 23 such that  
the top surface 42 of the control wheel 41 aligns while  
the horizontal plane of the outer surface of the body  
31 forms a unitary horizontal plane. The control wheel  
41 is also attached within the recessed portion 23 of  
the body 31 of the handle 30 at a level whereby the  
control wheel 41 can be rotated with the fingers of the  
hand holding the catheter body as shown in Figures 1  
and 2. The control wheel 41 is connected to the handle  
30 on the lower interior surface of the first cavity 34  
of the handle 30. This control wheel 41 is positioned  
so that it may be easily manipulated by the medical  
practitioner with the hand H which holds the catheter  
body 31. As illustrated in Figure 7, the control wheel  
41 is rotatably and fixedly connected to the recessed  
portion 23 of the body 31 for controlling the  
deflecting means 40 to thereby manipulate distal  
portions 58 of the elongate tube 55 within a human body  
B. The control means 40 further has control connector  
means connected to the control wheel 41 and detachably  
connected to the deflecting means 40 for connecting the  
control wheel 41 to the deflecting means 40.

The control wheel 41 is generally circular in  
shape and has a top surface 42 and a bottom surface 43.  
The wheel 41 preferably is configured to include an  
indented portion formed on each opposite vertical side  
of the control wheel 41 for manipulating the control

wheel 41. The indented portions 44 are shaped to receive a practitioner's finger F for rotating the control wheel 41 to manipulate portions of the elongate tube 55 within a human body. Preferably, the control wheel 41 is rotated between a thumb and third finger when the wheel 41 is held in the user's hand as best shown in Figures 1 and 2.

The control connector means 40 has deflection linkage wires 81, 82 each respectively connected to a shaft collar 46 of the control wheel 41. The control connector means further has deflection control pins 83 connected to the deflection linkage wires 81, 82 at a distal portion thereof. The deflection control pins 83 extend from the first cavity 34 through the wall 32. The deflection control pins 83 are detachably connected to the deflecting means 40 of the module 50. The control connector means preferably also has deflection springs 84 connected circularly and longitudinally around a medial portion of the deflection control pins 83. The control connector means allows the control wheel 41 to actuate the deflection linkage wires 82, the deflection linkage control pins 83, and the deflection springs 84 to control the deflecting means 40 so as to manipulate a portion of the elongate tube 55 within the body 31.

The control wheel 41 preferably includes a shaft 49 connected to the bottom surface 43 of the wheel 41 at a center axis 45 of the wheel 41 and extending laterally downwardly within the body 31 of the handle 30 as shown in Figure 7. The shaft 49 is rotatably connected to the body 31 and fixedly connected to the control wheel 41 such that the shaft 49 rotates in unison with the wheel 41 as it rotates. The control wheel 41 illustrated in Figures 7-10 further includes the shaft collar 46 extending longitudinally toward the proximal direction of the

handle 30. The shaft collar 46 includes a groove or an opening 48 as illustrated.

5 The deflection linkage wires 81, 82 preferably are fixedly connected to the shaft collar 46 of the control wheel 41 within the groove or opening 48. The deflection linkage wires 81, 82 extend around the control wheel 41 and toward the distal portion of the handle 30 and are fixedly connected to the proximal end of the shaft collar 46. The deflection linkage wires 81, 83 are connected in this embodiment and each includes a hooked portion 86 extending through and around an opening 88 in the proximal portion of the deflection control pins 83. The deflection control pins 83 preferably are connected to the deflection linkage wires 81, 82 and control wheel 41 within the first cavity 34 of the body 31. The deflection control pins 83 are disposed horizontally and extend toward the distal end portion 30a of the body 31. The deflection control pins 83 extend from within the first cavity 34, through the wall 32 of the body 31, and into the second cavity 38 as shown in Figure 6. Seals such as o-rings 39 preferably are positioned around each deflection control pin 83 between the pin 83 and the wall 32 to seal this opening from fluids and contaminants during use or sterilization.

25 Disposed around the deflection control pins 83 are the deflection tension springs 84 also illustrated in Figure 6. The deflection tension springs 84 interact with the wall 32 of the body 31 thereby providing resistance when the control wheel 41 is turned to actuate deflection of the tube 55. The detachable steerable catheter 20 according to an embodiment of the present invention shown in Figure 8 thereby includes a pair of these deflection control connector systems including the shaft collar 46 of the control wheel 41, deflection linkage wire 82, deflection control spring 84, and deflection control



pin 83 as shown in Figure 8. This pair of deflection linkage wires 82, deflection tension springs, and deflection control pins 83 are disposed on each side of the longitudinal axis of the body 31 shown in Figure 8.

5 The deflection control pins 83 each contain an opening 89 in the distal portion of the control pin 83 to receive the deflection means 40. The opening 89 laterally receives a steering wire end 73 located in the module 50.

10 The handle 30 preferably is sealed in all openings. The openings where the control wheel 41 and focus wheel 100 protrude from the body 31 also are sealed. In the embodiment of the present invention shown in Figures 7-10, O-rings 48a are located between

15 the control wheel 41 and the body edge portions and between the focus wheel 100 and the body edge portions for sealing the handle body 31 during use and sterilization. O-rings 39 are also positioned around the opening in the wall 32 of the body 31 where the

20 deflection control pins 83 extend through the wall 32 of the body 31 portion shown in Figure 7.

The detachable steerable catheter 20 according to the present invention further includes deflecting means 60 connected within the module 50.

25 These deflecting means 60 are shown in Figures 8-12. The embodiment illustrated in these figures shows the deflecting means 60 comprises pairs of steering wires 61, 62 having distal portions connected to the distal portions of the elongate tube 55 and proximal portions connected to the module interface 53. As the steering wires 61, 62 preferably are identical, they will be described in reference to one steering wire 61 or 62 where appropriate. The proximal portions of the steering wires 61, 62 preferably are positioned along a

30 proximal portion of the module interface 53. The module interface 53 is detachably connected to the body 31 such that proximal ends 73 of the steering wires 61

35

62 are detachably connected to the control means 40 to thereby manipulate distal end portions 58 of the distal elongate tube 55 positioned within a human body B when the control means 40 are operatively activated.

5 As shown in Figure 4, the steering wires 61, 62 extend from the lumen 67 of the module 50 and each includes a steering wire end 73. The steering wires 61, 62 preferably are positioned generally parallel to one another in the module 50. The steering wire ends 10 73 preferably are positioned on opposite sides of the scope lumen 69 of the tube 55. The steering wire ends 73 include a leg 71 which extends laterally from the module interface 53 and a post 54 disposed at the lateral edge portion of the steering wire end 73. The 15 post 54 extends downwardly so that when the module 50 and handle 30 are detachably connected, the post 54 is aligned to be received within the opening 89 of the deflection control pin 83.

20 Figures 11 and 12 illustrate the portions elongate tube 55 of the steerable catheter having a disposable module and a sterilizable handle and the construction of the steering wires 61, 62. The steering wires 61, 62 extend through wire lumens in the elongate tube 55 to the distal end portion 58 of the 25 elongate tube 55. In the distal end portion 58 of the tube 55, the steering wires 61, 62 are looped and extend parallel to each other in an upper and lower portion of the tube 55 as shown in Figure 12. Figure 12 is an enlarged cross-sectional view illustrating the 30 insertion of the steering wires 61, 62 prior to the forming of the tip (illustrated in phantom view) of the distal end portion 58 of the tube 55. Pairs of upper steering wire lumens and lower lumens are positioned on opposite sides of the working lumens 67, 68 and scope 35 lumen 69 within the tube 55 as shown in Figure 11. The steering wires 61, 62 are inserted into the wire lumens of the various portions of the tube 55 and form loops

in the distal end portion 58. The steering wires 61, 62 preferably are fixed to the elongate tube 55 so that the movement of the control wheel 41 responsively moves the steering wires 61, 62 to thereby bend and  
5 manipulate the tube 55. Numerous techniques can be used to fix the steering wires 61, 62 to the elongate tube 55 such as RF welding or welding ends of the wires 61, 62 to a portion such as the distal portion 58 of the elongate tube 55.

10 These techniques are understood by those skilled in the art. As illustrated in the embodiment of Figure 12, the looping of the steering wires 61, 62 through the wire lumens of the distal end portion 58 of the tube 55 secures the steering wires 61, 62 to a  
15 portion of the elongate tube 55 and also reduces the slippage of the steering wires 61, 62 as the steering wires 61, 62 are moved longitudinally with respect to one another to manipulate the various portions of the elongate tube 55. Figure 11 illustrates the location  
20 of the working lumens 67, 68, the scope lumen 69, and the steering wire lumens extending parallel to the axis of the coaxial proximal medial and distal portions and the steering wires 61, 62 positioned within the elongate tube 55.

25 As the control wheel 41 is actuated in one direction and thereby moves the control connector means in the same direction, the steering wires 61, 62 are moved to deflect the elongate tube 55 under tension in that direction. The tube 55 can be deflected in an  
30 arced path along about a 180° path. Various deflecting means other than steering wires 61, 62 positioned in the elongate tube 55 are known and could be incorporated within this embodiment of the detachable  
35 steerable catheter 20 as understood by the present invention.

The embodiment shown in Figures 5-20 further illustrates a module 50 including an engaging means 75

for detachably engaging the deflecting means 60 of the module 50 and the control means 40 of the handle 30 after the module 50 is detachably connected to the handle 30. This engaging means preferably is pivotally connected to the module interface 53. The engaging means is movable between a first disengaged position and a second engaged position. In the first disengaged position, the engaging means is not in contact with the deflecting means 60, and the deflecting means 60 and the control means 40 are not detachably connected as illustrated in Figure 5. Therefore, in the first disengaged position, the distal end portion 58 of the elongate tube 55 cannot be manipulated by actuating the control means 40.

In the second engaged position, the engaging means 75 guides or moves the deflecting means 60 to detachably connect to the control means 40. The engaging means 75 is pivotally moved to the second engaged position whereby the engaging means 75 engages the deflecting means 60 and detachably connects the deflecting means 60 to the control means 40 such that the control wheel 41 can be actuated to control the deflecting means 40 for manipulating the distal portion of the tube 55 in the human body B.

As shown in Figure 5, the engaging means 75 preferably has a tap 79 including a grip portion 75, 78 and an arm portion 74 hingedly connected to the module interface 53. In the unengaged position, the arm portion 74 is not in contact with the steering wire ends. The arm portion 74, however, is positioned such that when the grip portion 78 is grasped and the tap 79 is pivoted, the arm 74 moves in a generally downward direction toward the center of the opening 89. The arm portion 74 engages the steering wire end 73 and forces the post 54 of the steering wire end 87 into the opening 89 of the control pin 83 as shown in Figures 7 and 8. When the tap 79 is fully extended, a detachable

locking connection is formed between an edge portion of the tap 79 and an edge of the outer surface of the module 50 forming a single planar surface which preferably seals the module 50 from exposure to fluids, viruses, bacteria, and other elements.

The module 50 is provided with a tap 79 constructed of a suitable material for rotating from the disengaged to the engaged position described herein. Preferably, this portion of the module 50 is constructed from a flexible plastic which pivots without cracking or breaking. The tap 79 is integrally formed with the module 50. In the engaged position as shown in Figure 8, the steering wire posts 54 are detachably connected within the openings 89 of the control pin 83. As further shown in Figure 7, the steering wire ends 73 remain detachably connected within the openings 89 of the control pin 83 by the locking connection of the tap 79 with the edge of the outer surface of the body 31.

As such, the control wheel 41 can be rotated to deflect and manipulate portions of the elongate tube 55 within the human body B. As described, deflection of the distal end portion 58 of the elongate tube 55 occurs in a horizontal plane of 180° rotation. Manipulation can be actuated rotatably in vertical arc of 360° about the longitudinal axis of the tube 55 by rotating the hand H holding the handle 30 in either a clockwise or counterclockwise direction.

As shown in Figures 2 and 3A-C, the detachable steerable catheter 20 according to the present invention has a module interface including an upper proximal portion which connects to the medial portion 30C of the handle body 31. The module 50 includes a plurality of access ports 64, 65, 66. The ports are connected within the upper proximal portion and positionally aligned with at least one of the lumens 67 in the elongate tube 55 for accessing at

least one lumen 67 therefrom. The tube 55 has at least one lumen 67 which extends from the proximal end portion 56 of the elongate tube 55 to the distal end portion 50 of the tube. The elongate tube 55 has an opening 96 in the distal end portion shown in Figure 12. At least one lumen 67 is coaxially aligned with an opening in the distal tip 96 of the elongate tube 55 defining at least one, and preferably two or more, open channel extending from the access ports 64, 65, 66 through the lumen 67 into the opening for inserting fluids and instruments into the human body B.

The embodiment of the steerable catheter having a disposable module and a sterilizable handle according to the present invention as illustrated in Figures 2 and 3A-3D includes three access ports 64, 65, 66 positioned in the upper surface of the module interface 53. These access ports 64, 65, 66 are positionally aligned with two lumens 67, 68 defining relatively straight channels whereby medical instruments I and fluids can be inserted through the access ports 64, 65, 66 into the lumen 67, 68 extending substantially straight from a user toward a distal end portion 58 of the tube 55.

Figure 3B, for example, shows this straight channel formed from the access port into the lumen. The embodiment shown in Figure 3B in combination with Figures 4 and 11 show three access ports 64, 65, 66 going through a manifold 120, best illustrated in Figure 4, into two upper lumens 67, 68 as shown in Figure 11. The catheter 20 according to the present invention can be provided with various numbers of access ports 64, 65, 66 and lumens 67, 68, 69. Further, the catheter 20 can be provided without a manifold 120 having equal numbers of ports and lumens. The catheter 20 according to the present invention, however, preferably has at least one working lumen 67

or 68 and one scope lumen 64 for the fiber optic scope 90.

As shown in Figure 3B, various attachments such as a fluid tube 132 with a standard medical luer lock 134 attached to its distal end can be connected within an access port 64 such that a medical device or apparatus such as an IV fluid tube can be connected to the luer lock 134 and inserted into the access port 64 and the elongate tube 55.

As shown in Figure 4, the module 50 includes a module interface 53 having a manifold 120 whereby piping connectors 122, 123, 124 extend from the access ports 64, 65, 66 into the lumens 67, 68 of the tube 55. Figure 4 shows three upper lumens 122, 123, 124 for inserting fluid and/or instruments. Figure 4 further shows a scope lumen 69 located below the working lumens 67, 68 for inserting a fiber optic scope 90 within the elongate tube 55. A preferred embodiment contemplates a module 50 having a manifold 120 positioned within the module 50. The manifold 120 includes a piping connector 121 having a plurality of openings connecting a plurality of the access ports 64, 65, 66 to at least one or a lesser number of the lumens 67, 68 of the elongate tube 55. The access ports 64, 65, 66 and the lumens 67, 68 are positionally aligned on opposite ends of the openings of the piping connector 121 defining a relatively straight channel whereby medical instruments I and fluids can be inserted through the access ports 64, 65, 66 into the lumen 67, 68 extending substantially straight from a user toward a distal end of the tube 55.

The module 50 is further provided with an upper face which includes a recessed portion 59. The access ports 64, 65, 66 preferably are positioned in an opening in the module interface 53 within this recessed portion as illustrated. In a preferred embodiment, as shown in Figure 3B, the outward openings of the access

ports 64, 65, 66 align with the upper surface of the recessed portion 59 defining a generally unitary plane between the access port openings and the surface of the recessed portion 59 of the upper face. The position of these access ports 64, 65, 66 in this recessed portion 59 is advantageous for inserting both medical instruments I and fluids as well as attaching a medical device or apparatus and connectors such as the tube 132 with luer lock 134 shown in Figure 3B.

The catheter 20 according to the present invention is provided in a preferred embodiment with an angled handle 30. The catheter 20 includes a handle 30 detachably connected to the module 50 and configured to be readily held in the hand H of a user. The handle 30 has a body 31 including proximal 30b, medial 30c, and distal 30a portions. The body 31 preferably angles, as shown in Figure 6, from the proximal portion toward the distal portion along an upper surface and a lower surface of the body 31. This angling of the handle defines an angle  $\theta$ , e.g., preferably between 5°-60°, between the tube 55 and the portion of the body 31 held by the medical practitioner for facilitating inserting the catheter 20 into a vessel, cavity, or tissue of the human body.

Various surgical and diagnostic procedures require inserting the detachable steerable catheter 20 into openings at various angles. The angled handle 30 facilitates the medical practitioner's ability to maintain his hand, wrist, and forearm in an advantageous straight alignment allowing the angle of the handle 11 to position the tube 55 within the opening. This facilitates both the ease and precision of use, as well as comfort for the patient and practitioner. Also, this angling provides other ergonomic advantages such as reducing fatigue on the practitioner during lengthy or repeated procedures.



Various angled configurations could be provided having the ergonomic advantages of the preferred embodiment.

Other ergonomic advantages are provided by the catheter 20 according to the present invention.

5 For example, the distribution and weight of the catheter 20 according to the present invention is such that it can effectively be used as a single hand-held unit. The angling and weight distribution of the catheter also enhance the usability of the control  
10 wheel 41 and focus wheel 100. The catheter 20 according to the present invention is designed such that the focus wheel 100 and control wheel 41 can be simultaneously activated to manipulate the elongate tube 55 as illustrated in Figure 2.

15 Further, the detachable steerable catheter 20 according to the present invention, as illustrated in Figure 8, comprises a body 31 including vertical sides. The body 31 tapers inwardly from the distal portion 30a toward a medial portion 30c along the vertical sides  
20 and from a proximal portion 30b toward a medial portion 30c along the vertical sides. This taper also facilitates holding and manipulation of the detachable steerable catheter 20 by a single hand. The embodiment illustrated includes a narrow portion enabling the  
25 practitioner to grip the handle 30 around the medial portion 30c between the thumb and fingers to rotatively control the control wheel 41.

30 The handle 30 is also provided to be held near the medial portion 30c of the body 31 with the weight distribution such that the handle 30 remains balanced within the practitioner's palm during use. Such a long instrument as the catheter 20, if not  
35 balanced, would tend to flop in a forward or rearward direction out of the practitioner's hand during use. Further the catheter 20 is lightweight. The handle 30 material preferably includes a thermoplastic or a thermoset or a metal/metal alloy (such as aluminum or

stainless steel). Various other angled handle 11 configurations could be provided with the described ergonomic advantages.

5 The steerable catheter having a disposable module and a sterilizable handle according to the present invention also has imaging means 150 positioned within the body 31 of the handle 31 for transmitting images from within the human body B to an external viewing apparatus such as a monitor or CRT as shown in 10 Figures 3A-3D and 7-10. The medical practitioner can thereby view a space within the human body B while simultaneously conducting medical procedures or diagnosis.

15 Figure 7 illustrates a steerable catheter 20 having a disposable module and a sterilizable handle according to the present invention with an imaging cable 89 detachably connected to the imaging means 150, such as an internally disposed camera 156 and internal interface cable 157, through an opening or port 36 in 20 the proximal end portion 30b of the handle 30. The imaging cable 89 extends outwardly from the catheter 20 and connects at its opposite end to a viewing monitor or CRT as known in the art for transmitting images from within the human body for viewing on the attached 25 monitor.

30 An embodiment of the detachable steerable catheter 20 according to the present invention preferably includes imaging means which includes a camera 156 positioned within the first cavity 34 of the body 31 of the catheter 20 for capturing and transmitting images from within the body as illustrated in Figures 7-10. The handle 31 is sealed to protect the camera 156 from contaminants. The camera 156 also is sealed to withstand sterilization and use without 35 damaging the camera. Although not preferable, other imaging means such as an external camera could be used in conjunction with the detachable steerable catheter

20 to capture and transmit images from within the human body during the medical procedure according to the present invention.

5 The imaging interface cable 157 includes an image bundle and light source bundle. The imaging interface cable 157 connects to the proximal portion of the camera 156 and extends rearwardly around the shaft 49 of the focus wheel 100 and control wheels 41 as illustrated in the fragmentary sectional view of Figure 9. The imaging interface cable 157 extends further rearwardly and connects to the image connector 159 positioned in the image port located in the proximal opening of the handle 31 as shown in Figure 7. This image connector connects to the external imaging cable 15 89 which includes a corresponding light source and image bundle for transmitting images from within the human body B to the external monitor.

20 The imaging interface 25 preferably is connected to the distal end of the camera 156. The imaging interface 25 preferably extends through the wall 32 of the body 31. As illustrated in Figure 8, the camera 156 is disposed within the proximal portion of the handle body 31 and within the first cavity 34. The camera 156 is also disposed between the control connector means as also shown in Figure 8. The camera 25 156 extends rearwardly toward the medial portion of the body 31. The imaging interface cable 157 extends rearwardly around the shaft 49 of the control wheel 41 to connect with the image cable 89 in the proximal opening 36 of the detachable steerable catheter 20 as illustrated in Figure 9.

30 A preferred embodiment of the steerable catheter 20 having a disposable module and a sterilizable handle according to the present invention is utilized with a fiber optic scope 90 as described in connection with Figures 3A through 3D. Other means of projecting light or receiving images, however, could 35

also be provided. Fiber scopes of varying dimensions can be provided to match various sized elongate tubes utilized for different procedures. The fiber optic scope 90 provided is preferably between 8 and 14 inches in length. In a preferred embodiment, such as illustrated in Figure 6, the fiber optic scope 90 connection with the imaging interface 25 aligns the fiber optic material, e.g., along flange 94a, of the fiber optic scope 90 with the light source bundle and camera 156 connected to the handle imaging interface. The fiber optic scope 90 comprises a portion of fiber optic material which is centered on the camera 156. The fiber optic scope 90, or fiber scope, is also aligned with light sources within the imaging interface. The fiber scope 90 magnifies the light transmitted down the length of the elongate tube 55 from the light source. Further, the fiber optic scope 90 receives images from within the human body B and transmits them to the camera 156 connected to the fiber optic scope 90.

In conjunction with the imaging means of a preferred embodiment, the detachable steerable catheter 20 also has focus means 100 for focusing images transmitted from within the human body during a medical procedure or diagnosis. This focus means 100 preferably includes a focus wheel 101 having a top surface and a bottom surface whereby images are easily adjusted or focused using a single finger F to rotate the top surface of the wheel 101 as shown in Figure 2. The focus wheel 101 includes an indentation 104 configured to receive a finger F as shown in Figures 2 and 3 for rotating the focus wheel 101 to focus images transmitted from within the human body. The medical practitioner can thereby easily focus the images transmitted from within the human body on the catheter 20 while viewing the images on the attached monitor.

The focus wheel 101 preferably is positioned on the upper surface of the body 31 in proximity to the deflecting control wheel 41 such as to facilitate focusing and controlling by a single hand H of the practitioner or by another practitioner. The catheter 20 according to the present invention overcomes prior problems of focusing an external camera requiring moving away from the space of the actual procedure or relying on another practitioner or assistant for focusing.

The focus means 100 further includes a focus connector fixedly connected to a bottom surface of the focus wheel 101 such that the shaft 108 and the focus wheel 101 rotate in unison (see Figure 9). The shaft 108 extends downwardly within the first cavity 34 of the body 31 and is connected to the body 31 on the bottom of the body 31.

The control wheel 41 contains a recessed center portion of the upper surface. The focus wheel 101 is positioned concentrically within this recessed portion of the control wheel 41 as illustrated in Figure 10. The focus wheel 101 is connected to the body 31 in the recessed portion of the control wheel 41 such that the focus wheel 101 and the control wheel 41 define generally concentric circles and are aligned defining a generally common center portion of each wheel with the imaging focus wheel 101 having a smaller diameter than the control wheel 41. The focus wheel 101 and control wheel 41 rotate independently. Various other shapes and configurations of this catheter 20 having a focus wheel 101 according to the present invention could be provided. The upper surface of the focus wheel 101 and the control wheel 41 preferably form a unitary plane.

Figures 7, 8, 9, and 10 illustrate other aspects of an embodiment of the focusing means. The focusing means further comprises, in this embodiment, a

focus cable 109 connected to the shaft 108 of the focus wheel 101. The camera 156 includes an imaging focus means which when actuated by rotating the focus wheel 101 rotates to focus the images. This allows the focus wheel 101 to be rotated beyond a full 360° in a single direction to facilitate focusing. Preferably, when the focus wheel 101 is turned beyond about 15-30°, e.g., about 22.5°, for example, the image is inverted and the imaging means continues to focus the image as viewed. Figure 9 shows the focus cable 109 connected to the shaft 108 of the focus wheel 101 for translating the rotational movement of the focus wheel 101 into linear movement of focusing a focus cell or other means within the cavity 34 for focusing the image.

The steerable catheter having a disposable module and a sterilizable handle according to the present invention can also be supplied in another embodiment as a catheter kit 200. The detachable steerable catheter kit 200 provides a catheter 20 for inserting at least portions into a vessel, cavity, or tissue of the human body B to thereby provide disposability and manipulation of a portion of the catheter 20 when positioned within the vessel, cavity, or tissue. The kit 200 comprises a plurality of disposable modules 50 and a reusable handle 30 for detachably connecting to the modules 50. The handle 30 is configured to be readily held in the hand H of a user as described above.

The detachable steerable catheter kit 200 further comprises a fiber optic scope 90 which can be detachably connected to the handle 30 and positionable within the module 50 as previously described. The module 50 of this kit 200 would include an elongate tube 55 having at least one lumen 67, 68 extending from a distal end 58 to the proximal end 56 of the tube 55, a module interface 53 connected to the proximal end 56 of the tube 55, and deflecting means 60 connected to

the tube 55 for deflecting the distal portion of the elongate tube 55. The reusable handle 30 has a body 31 including a wall 32 positioned in distal portions of the body 31; the wall 32 has an outer surface thereof defining an exterior portion of the body 31. A first cavity 34 is formed within the body 31. The body 31 is detachably and extensively connectable to the module interface 53 through the outer surface of the wall 32. The handle 30 also has control means 40 connected to the body 31 and detachably connected to the deflecting means 60 of the module 50 for responsively controlling the deflecting means 60 to thereby manipulate distal portions of the elongate tube 55. The control means 40 and deflecting means 60 define a unitary catheter manipulation means extending from the first cavity 34 through the wall 32 and to the tube 55 for manipulating a distal portion of the catheter 20 when positioned in a vessel, cavity, or tissue.

This catheter kit 20 is illustrated in Figures 13 and 14. Figure 13 illustrates a module 50 as described above sealed within a plastic packaging. Figure 14 illustrates a plurality of these disposable individually sealed modules 50 inserted within a package with a sealed reusable handle 30 and a sealed reusable fiber scope 90 both as explained previously. Other configurations of the kit 200 can be sold. For example, a kit can be sold without a fiber scope 90 or with a plurality of varying sized fiber scopes 90 and modules 50. As indicated, the fiber optic scope 90 and module 50 vary in length, diameter, and configuration according to the end application. This kit 200 will facilitate ease of use as a catheter 20 and included camera 156 which can all be shipped, stored, and used in a small space. The catheter kit 20 according to the present invention also provides the advantage of saving space such as during shipping, storage, and use.

The present invention also includes methods of connecting and using a catheter 20 as described above and as illustrated in the drawings. A method of detachably connecting a catheter 20 having a handle 30 which includes a body 31 and a detachable module 50 which includes an elongate tube 55 having at least one lumen 67, 68, 69 extending therethrough is provided by the present invention. This method preferably includes connecting a fiberscope 90 to a distal end portion of the body 31 of the handle 30, positioning the fiberscope 90 into the at least one lumen 69 of the tube 55 of the module 50, and connecting the module 50 to the body 31 of the handle for viewing portions of a vessel, cavity, or tissue when a distal end of the tube 55 is positioned therein.

The catheter 20 and methods of the present invention further provide a detachable catheter with a reusable fiber optic scope 90 which can be detachably connected to the handle 30 and sealed within the detachable module 50 during a medical procedure. A steerable catheter 20 having a disposable module 50 and a sterilizable handle 30 according to the present invention also can advantageously be provided in a kit 200 which, for example, includes a plurality of detachable, disposable modules 50 and a reusable handle 30 and also may include a fiber optic scope 90 to be used with the disposable modules. The kit 200, for example, provides the practitioner with an apparatus and method which allow a first module 50 to be connected to the handle 30 for use in a cavity, vessel, or tissue during a medical procedure such as a gynecological, epidural, neurological, nose, brain, cardiovascular, thoracic, or other procedure as understood by those skilled in the art. The first module 50 can then be disconnected and disposed of by placing it into a sanitary container or other means of properly disposing of a used and/or contaminated



device. The handle 30 can then be sterilized and a second module, e.g., sterile module from the kit 200, connected to the body 31 of the handle 30.

The handle 30 of a steerable catheter 20 according to the present invention can further include the angled handle that provides entry, e.g., preferably along a substantially straight axis, into a portion of the human body while allowing the medical practitioner to grasp the steerable catheter in an advantageous hand position. A detachable steerable catheter 20 can also advantageously include the camera 156 mounted internally in the handle of the catheter wherein the handle can be sterilized with the camera therein and the camera is protected from breakage or contamination therein. A steerable catheter and methods according to the present invention further can provide a steerable catheter having a focus means positioned on the handle of the catheter for focusing the internal camera positioned within the handle. A steerable catheter 20 and methods of the present invention also advantageously provide a disposable module and a sterilizable handle having a focus wheel and control wheel disposed such that the focus wheel and control wheel can be simultaneously adjusted by the same hand of the practitioner.

In the drawings and specification, there have been disclosed preferred embodiments of the invention, and, although specific terms are employed, these terms are used in a descriptive sense only and not for purposes of limitation. The invention has been described in considerable detail with specific reference to various illustrated embodiments. It will be apparent, however, that various modifications and changes can be made within the spirit and scope of the invention as described in the foregoing specification and defined in the appended claims.

THAT WHICH IS CLAIMED:

1. A catheter for inserting at least portions thereof into a vessel, cavity, or tissue of a human body to thereby provide manipulation of a distal end portion of the catheter when positioned within a vessel, cavity, or tissue, the catheter comprising:

a module including an elongate tube having at least one lumen extending from a distal end portion to a proximal end portion of said tube, a module interface connected to the proximal end portion of said tube, and deflecting means connected to said tube for deflecting the distal end portion of said elongate tube; and

a handle detachably connected to said module and configured to be readily held in the hand of a user, said handle comprising a body including a first cavity formed within said body and a wall transversely extending across portions of said body and defining distal peripheral portions of said first cavity, and control means connected to said body and detachably connected to said deflecting means of said module through said wall of said body for responsively controlling said deflecting means to thereby manipulate distal portions of said elongate tube, said control means and said deflecting means being connected to define a unitary catheter manipulation means extending from said first cavity, through said wall, and to said elongate tube for manipulating a distal portion of the catheter when positioned within a vessel, cavity, or tissue.

2. A catheter as defined in Claim 1, wherein body and said module interface detachably connect to define a second cavity having peripheries which include an outer surface of said wall and an inner surface of said module interface, said control means and said deflecting means being detachably connected within said second cavity so that said

unitary catheter manipulation means extends from said first cavity, through said wall, through said second cavity, and to said elongate tube for manipulating a distal portion of the catheter when positioned within a vessel, cavity, or tissue.

3. A catheter as defined in Claim 1, wherein at least proximal portions of said module interface coextensively overlies distal portions of said body of said handle such that said body and said module interface define a unitary catheter body having sufficient stability for easily manipulating of said unitary catheter body by a user thereof.

4. A catheter as defined in Claim 1, wherein said module interface further comprises proximal, non-uniform peripheries, and wherein said body of said handle further comprises distal, non-uniform peripheries positionally aligning with said non-uniform peripheries of said module interface, said non-uniform peripheries of said module interface being detachably connected to said non-uniform peripheries of said distal portion of said body so as to define a non-uniform contiguous boundary between said module and said handle whereby said module is stabilized relative to said handle during manipulation of said tube within a human body.

5. A catheter as defined in Claim 1, wherein said handle further comprises an imaging interface positioned in the proximal portion of said body, said imaging interface extending from within said first cavity through said wall, and image capturing means positioned within said first cavity and being connected to said imaging interface for capturing images, and wherein said catheter further comprises a fiber optic scope detachably connected to said imaging

10 interface of said handle and positioned in said at  
least one lumen of said tube and extending from the  
proximal end portion of said tube to the distal end  
portion thereof for receiving images within a human  
body and for providing light into the vessel, cavity,  
15 or tissue of a human body.

6. A catheter as defined in Claim 1,  
wherein said elongate tube of said module further  
comprises a plurality of lumens and wherein said module  
interface surface comprises a plurality of access ports  
5 formed in an outer surface of said module interface  
being positionally aligned with said plurality of  
lumens for accessing said plurality of lumens therefrom  
to insert fluids and instruments into a cavity, vessel,  
or tissue of a human body.

7. A catheter as defined in Claim 1,  
wherein said body of said handle includes a proximal  
portion, a medial portion integrally connected to said  
proximal portion, and a distal portion integrally  
5 connected to said medial portion, said module being  
detachably connected to at least distal portions of  
said body of said handle, said at least distal portions  
of said body being positioned at a predetermined angle  
from said proximal portion, and from said module  
10 interface further includes at least one access port  
positionally aligned with said at least one lumen so as  
to define a relatively straight channel whereby medical  
instruments and fluids can be inserted through said  
access port and into said at least one lumen, and  
15 extend through said at least one lumen along a  
substantially straight path from a user toward a distal  
end of said tube.

8. A catheter as defined in Claim 8,  
wherein said module interface further includes a

manifold including a piping connector having a plurality of openings therein, said piping connector connecting at least two of said plurality of said access ports to one of said plurality of lumens of said elongate tube, said access ports and said one of said plurality of lumens being positionally aligned on opposite ends of said openings of said piping connector defining a relatively straight channel whereby medical instruments and fluids can be inserted through said access port, into said one of said plurality of lumens, and extend through said one of said plurality of lumens along a substantially straight path from a user toward a distal end of said tube.

9. A catheter as defined in Claim 1, wherein said body includes a recess portion formed in a medical portion thereof, and wherein said control means comprises a control wheel rotatably mounted to said recess portion of said body for controlling said deflecting means to thereby manipulate distal portions of said elongate tube within a human body and control connector means responsively connected to said control wheel and responsively and detachably connected to said deflecting means for connecting said control wheel to said deflecting means to thereby manipulate distal end portions of said elongate tube when positioned within a human body.

10. A catheter as defined in Claim 12, wherein said control connector means comprises at least one deflection linkage wire fixedly connected to said control wheel and extending from said control wheel toward said distal portion of said body within said first cavity, a deflection control pin fixedly connected to said at least one deflection linkage wire in a proximal portion of said deflection control pin, said deflection control pin extending from said first

10 cavity through said wall, said deflection control pin  
being detachably connected to said deflecting means of  
said module so that said control wheel thereby  
responsively actuates said deflection linkage wire and  
said deflection control pin to control said deflecting  
15 means for manipulating a distal end portion of said  
elongate tube when positioned within a human body.

11. A catheter as defined in Claim 1,  
wherein said deflecting means comprises a pair of  
steering wires having distal portions positioned in a  
distal portion of said elongate tube and proximal  
5 portions positioned in said module interface, said  
proximal end portions being operatively and detachably  
connected to said control means to thereby responsively  
manipulate distal end portions of said elongate tube  
when positioned within a human body.

12. A catheter as defined in Claim 1,  
wherein said module further comprises engaging means  
for detachably engaging said deflecting means and said  
control means, said engaging means being hingedly  
5 connected to said module interface, said engaging means  
being movable between a first disengaged position  
having said engaging means spaced apart from said  
deflecting means and a second engaged position having  
said engaging means contactingly engage said deflection  
10 means such that said deflection means is detachably  
connected to said control means for manipulating the  
distal portion of said tube within a human body.

13. A catheter for inserting at least  
portions thereof into a vessel, cavity, or tissue of a  
human body to thereby provide manipulation of a distal  
end portion of the catheter when positioned within a  
5 vessel, cavity, or tissue, the catheter comprising:

a module including an elongate tube having at least one lumen extending from a distal end portion to a proximal end portion of said tube, a module interface connected to the proximal end portion of said tube, and a deflector connected to said tube for deflecting the distal end portion of said elongate tube; and

a handle detachably connected to said module and configured to be readily held in the hand of a user, said handle comprising a body including a first cavity formed within said body and a wall transversely extending across portions of said body and defining distal peripheral portions of said first cavity, and a controller connected to said body and detachably connected to said deflector of said module through said wall of said body for responsively controlling said deflector to thereby manipulate distal portions of said elongate tube, said controller and said deflector being connected to define a unitary catheter manipulator extending from said first cavity, through said wall, and to said elongate tube for manipulating a distal portion of the catheter when positioned within a vessel, cavity, or tissue.

14. A catheter as defined in Claim 13, wherein body and said module interface detachably connect to define a second cavity having peripheries which include an outer surface of said wall and an inner surface of said module interface, said controller and said deflector being detachably connected within said second cavity so that said unitary catheter manipulator extends from said first cavity, through said wall, through said second cavity, and to said elongate tube for manipulating a distal portion of the catheter when positioned within a vessel, cavity, or tissue.

15. A catheter as defined in Claim 14,  
wherein at least proximal portions of said module  
interface coextensively overlies distal portions of said  
body of said handle such that said body and said module  
5 interface define a unitary catheter body having  
sufficient stability for easily manipulating of said  
unitary catheter body by a user thereof.

16. A catheter as defined in Claim 15,  
wherein said module interface further comprises  
proximal, non-uniform peripheries, and wherein said  
body of said handle further comprises distal, non-  
5 uniform peripheries positionally aligning with said  
non-uniform peripheries of said module interface, said  
non-uniform peripheries of said module interface being  
detachably connected to said non-uniform peripheries of  
said distal portion of said body so as to define a non-  
10 uniform contiguous boundary between said module and  
said handle whereby said module is stabilized relative  
to said handle during manipulation of said tube within  
a human body.

17. A catheter as defined in Claim 16,  
wherein said handle further comprises an imaging  
interface positioned in the proximal portion of said  
body, said imaging interface extending from within said  
5 first cavity through said wall, and an image capture  
device positioned within said first cavity and being  
connected to said imaging interface for capturing  
images, and wherein said catheter further comprises a  
fiber optic scope detachably connected to said imaging  
10 interface of said handle and positioned in said at  
least one lumen of said tube and extending from the  
proximal end portion of said tube to the distal end  
portion thereof for receiving images within a human  
body and for providing light into the vessel, cavity,  
15 or tissue of a human body.



18. A catheter as defined in Claim 17,  
wherein said elongate tube of said module further  
comprises a plurality of lumens and wherein said module  
interface surface comprises a plurality of access ports  
5 formed in an outer surface of said module interface  
being positionally aligned with said plurality of  
lumens for accessing said plurality of lumens therefrom  
to insert fluids and instruments into a cavity, vessel,  
or tissue of a human body.

19. A catheter as defined in Claim 18,  
wherein said body of said handle includes a proximal  
portion, a medial portion integral connected to said  
proximal portion, and a distal portion integrally  
5 connected to said medial portion, said module being  
detachably connected to at least distal portions of  
said body of said handle, said at least distal portions  
of said body being positioned at a predetermined angle  
from said proximal portion, and from said module  
10 interface further includes at least one access port  
positionally aligned with said at least one lumen so as  
to define a relatively straight channel whereby medical  
instruments and fluids can be inserted through said  
access port and into said at least one lumen, and  
15 extend through said at least one lumen along a  
substantially straight path from a user toward a distal  
end of said tube.

20. A catheter as defined in Claim 19,  
wherein said module interface further includes a  
manifold including a piping connector having a  
plurality of openings therein, said piping connector  
5 connecting at least two of said plurality of said  
access ports to one of said plurality of lumens of said  
elongate tube, said access ports and said one of said  
plurality of lumens being positionally aligned on  
opposite ends of said openings of said piping connector

10 defining a relatively straight channel whereby medical  
instruments and fluids can be inserted through said  
access port, into said one of said plurality of lumens,  
and extend through said one of said plurality of lumens  
15 along a substantially straight path from a user toward  
a distal end of said tube.

21. A catheter as defined in Claim 20,  
wherein said body includes a recess portion formed in a  
medical portion thereof, and wherein said controller  
comprises a control wheel rotatably mounted to said  
5 recess portion of said body for controlling said  
deflector to thereby manipulate distal portions of said  
elongate tube within a human body and a controller  
connector responsively connected to said control wheel  
and responsively and detachably connected to said  
10 deflector for connecting said control wheel to said  
deflector to thereby manipulate distal end portions of  
said elongate tube when positioned within a human body.

22. A catheter as defined in Claim 21,  
wherein said controller connector comprises at least  
one deflection linkage wire fixedly connected to said  
control wheel and extending from said control wheel  
5 toward said distal portion of said body within said  
first cavity, a deflection control pin fixedly  
connected to said at least one deflection linkage wire  
in a proximal portion of said deflection control pin,  
said deflection control pin extending from said first  
10 cavity through said wall, said deflection control pin  
being detachably connected to said deflector of said  
module so that said control wheel thereby responsively  
actuates said deflection linkage wire and said  
deflection control pin to control said deflector for  
15 manipulating a distal end portion of said elongate tube  
when positioned within a human body.

23. A catheter as defined in Claim 22,  
wherein said deflector comprises a pair of steering  
wires having distal portions positioned in a distal  
portion of said elongate tube and proximal portions  
positioned in said module interface, said proximal end  
portions being operatively and detachably connected to  
said controller to thereby responsively manipulate  
distal end portions of said elongate tube when  
positioned within a human body.

24. A catheter as defined in Claim 23,  
wherein said module further comprises engaging means  
for detachably engaging said deflector and said  
controller, said engaging means being hingedly  
connected to said module interface, said engaging means  
being operatively movable between a first disengaged  
position having said engaging means spaced apart from  
said deflecting means and a second engaged position  
having said engaging means contactingly engage said  
deflection means such that said deflector is detachably  
connected to said controller for manipulating the  
distal portion of said tube within a human body.

25. A catheter for inserting at least  
portions thereof into a vessel, cavity, or tissue of a  
human body to thereby provide manipulation of a distal  
portion of the catheter when positioned within a  
vessel, cavity, or tissue, the catheter comprising:

a module including an elongate tube having at  
least one lumen extending from a distal end portion to  
a proximal end portion of said tube and a module  
interface connected to the proximal end of said tube;

a handle detachably connected to said module  
and configured to be readily held in the hand of a  
user, said handle comprising a body including a wall  
positioned in and transversely extending across distal  
portions of said body, said wall having an outer

15 surface thereof defining an exterior portion of said  
body, and a first cavity formed within said body, said  
body being detachably and coextensively connected to  
said module interface through the outer surface of said  
20 wall, and an imaging interface located in the proximal  
portion of said body, said imaging interface extending  
from within said first cavity through said wall; and  
a fiber optic scope detachably connected to  
said imaging interface of said handle for receiving  
25 images within a human body and providing light into the  
vessel, cavity, or tissue of a human body, said fiber  
optic scope positioned within said at least one lumen  
of said tube and extending from the proximal end  
portion of said tube to the distal end portion thereof.

26. A catheter as defined in Claim 31,  
wherein said handle further comprises an image  
capturing device positioned within said first cavity  
and connected to said imaging interface for capturing  
5 images from said fiber scope received from within a  
vessel, cavity, or tissue of the human body.

27. A catheter as defined in Claim 31,  
wherein said module further comprises a deflector  
connected to said tube for deflecting the distal end  
portion of said elongate tube, and wherein said handle  
5 further comprises a controller connected to said body  
and detachably connected to said deflector of said  
module for responsively controlling said deflector  
means to thereby manipulate distal portions of said  
elongate tube, said controller and said deflector  
10 being connected to define a unitary catheter  
manipulator extending from said first cavity, through  
said wall, and to said tube for manipulating a distal  
portion of the catheter when positioned within a  
vessel, cavity, or tissue.

28. A catheter as defined in Claim 31,  
wherein said outer surface of said wall and a lower  
surface of said module interface detachably connect to  
define a second cavity, said fiber optic scope being  
connected to said imaging interface of said handle  
within the second cavity.

29. A catheter as defined in Claim 32,  
wherein said handle further comprises an opening  
positioned in a proximal end portion of said handle and  
providing access to said first cavity, and an internal  
interface cable having at least portions thereof  
positioned in said first cavity, connected to said  
image capture device, and extending from said first  
cavity and at least toward said proximal opening of  
said handle for connecting to an image viewing device  
so as to readily view images within a human body  
captured by said image capturing device and for  
providing a light path into the vessel, cavity, or  
tissue of a human body.

30. A catheter for inserting at least  
portions thereof into a vessel, cavity, or tissue of a  
human body to thereby provide manipulation of a distal  
portion of the catheter when positioned within a  
vessel, cavity, or tissue, the catheter comprising:

a module including an elongate tube having at  
least one lumen extending from a distal end to a  
proximal end of said tube and a module interface  
connected to the proximal end portion of said tube; and

a handle detachably connected to said module  
and configured to be readily held in the hand of a  
user, said handle comprising a body including a wall  
positioned in and extending transversely across distal  
portions of said body, said wall having an outer  
surface thereof defining an exterior portion of said  
body, and a first cavity formed within said body, said

20 body being detachably and coextensively connected to  
said module interface through the outer surface of said  
wall, an imaging interface connected to said body  
within said first cavity and extending through said  
wall, and an image capturing device connected to said  
imaging interface and positioned within said first  
cavity for capturing images from within a vessel,  
cavity, or tissue of the human body.

5 31. A catheter as defined in Claim 36,  
wherein said imaging means includes sealing means for  
sealing said imaging means from water and heat for  
sterilizing said handle with said imaging means  
positioned within said body of said handle.

5 32. A catheter according to Claim 36,  
wherein said handle body includes a recess in an upper  
surface, and said handle further comprises imaging  
focus means rotatably connected to said body in said  
recess, said imaging focus means connected to said  
imaging means within said first cavity for focusing  
images transmitted from within a vessel, cavity, or  
tissue of the human body.

5 33. A catheter according to Claim 37,  
wherein said imaging focus means comprises a focus  
wheel having a top surface and a bottom surface and a  
shaft fixedly connected to said focus wheel and  
extending downwardly into said first cavity of said  
body, said shaft being rotatably connected to said body  
in said recess such that said focus wheel is rotatable  
for focusing images transmitted from within a vessel,  
cavity, or tissue of a human body.

34. A catheter according to Claim 39,  
wherein said focus wheel further comprises an  
indentation in said upper surface configured to receive

5 a human finger whereby said focus wheel can be rotated  
for focusing images transmitted from within a vessel,  
cavity, or tissue of a human body.

35. A catheter according to Claim 36,  
wherein said module further comprises deflecting means  
connected to said tube for deflecting the distal  
portion of said elongate tube and wherein said handle  
5 further comprises control means connected to said body  
and detachably connected to said deflecting means of  
said module for responsively controlling said  
deflecting means to thereby manipulate distal portions  
of said elongate tube, said control means comprises a  
10 control wheel including a recessed center portion in  
the upper surface, said imaging focus wheel is  
connected to said body in said recess of said control  
wheel such that said focus wheel and said control wheel  
define generally concentric circles and are aligned  
15 defining a common center portion with said imaging  
focus wheel having a diameter smaller than said control  
wheel such that said focus wheel and said control wheel  
rotate independently and are in proximity for  
facilitating focusing images and manipulating the  
20 distal portion of the tube with the human body by a  
single medical practitioner.

36. A catheter for inserting at least  
portions thereof into a vessel, cavity, or tissue of a  
human body to thereby provide manipulation of a distal  
portion of the catheter when positioned within a  
5 vessel, cavity, or tissue, the catheter comprising:

a module including, an elongate tube having  
at least one lumen extending from a distal end to a  
proximal end of said tube, a module interface connected  
to the proximal end of said tube; and

10 a handle detachably connected to said module  
and configured to be readily held in the hand of a

user, said handle comprising a body including a proximal portion, a medial portion connected to and integrally formed with said proximal portion, and a distal portion connected to and integrally formed with said medial portion, said distal portion of said body being angularly disposed from said proximal portion of said body so as to define an angle between said distal portion and said proximal portion of said body for facilitating inserting the catheter into a vessel, cavity, or tissue within a human body.

37. A catheter defined in Claim 36, wherein said module further comprises deflecting means connected to said tube for deflecting the distal portion of said elongate tube, and said handle further comprises control means connected to said body and detachably connected to said deflecting means of said module for responsively controlling said deflecting means to thereby manipulate distal portions of said elongate tube for manipulating a distal portion of the catheter when positioned within a vessel, cavity, or tissue, and focus means mounted on said body for focusing images received from within the human body such that said focus means and said control means can be actuated using one hand while holding the catheter in the second hand.

38. A catheter as defined in Claim 36, wherein a distal portion of said body comprises a bulbous shape.

39. A steerable catheter kit comprising:  
a plurality of disposable modules, each said disposable module including an elongate tube having at least one lumen extending from a distal end to a proximal end of said tube, a module interface connected to the proximal end of said tube, and deflecting means



connected to said tube for deflecting the distal portion of said elongate tube; and

10 a reusable handle detachably connectable to said module and configured to be readily held in the hand of a user, said handle comprising a body including a wall positioned in distal portions of said body, said wall having an outer surface thereof defining an exterior portion of said body, and a first cavity  
15 formed within said body, said body being detachably and coextensively connectable to said module interface through the outer surface of said wall, and control means connected to said body and detachably connectable to said deflecting means of said module for  
20 responsively controlling said deflecting means to thereby manipulate distal portions of said elongate tube, said control means and said deflecting means being connectable to define a unitary catheter manipulation means extending from said first cavity,  
25 through said wall, and to said tube for manipulating a distal portion of the catheter when positioned within a vessel, cavity, or tissue.

40. A method of detachably connecting a catheter having a handle and a detachable module, the module including an elongate tube having at least one lumen extending therethrough and the handle including a  
5 body, the method comprising:

connecting a fiberscope to a distal end portion of the body of the handle;

positioning the fiberscope into the at least one lumen of the tube of the module; and

10 connecting the module to the body of the handle for viewing portions of a vessel, cavity, or tissue when a distal end of the tube is positioned therein.

41. A method as defined in Claim 40, further comprising capturing images of portions of a vessel, cavity, or tissue from an image capturing device positioned within the body of the handle.

42. A method as defined in Claim 41, further comprising focusing the images captured by said image capturing device from a focusing device connected to the body of the handle.

43. A method of using a catheter positioned in a hand of a user, the catheter having portions thereof positioned within a cavity, vessel, or tissue of a human body, the catheter including a handle configured to be readily held in a hand of a user and having a body, an elongate tube connected to and extending outwardly from the body of the handle, the elongate tube having at least one lumen extending therethrough from a proximal end portion to a distal end portion thereof, and a manipulator connected to the body of the handle and a distal end portion of the elongate tube, the method comprising:

positioning the elongate tube into a cavity, vessel, or tissue of a human body;

manipulating a distal end portion of the elongate tube responsive to a hand of a user holding the handle;

capturing an image of portions of a cavity, vessel, or tissue from the tube positioned in a cavity, vessel, or tissue; and

focusing the images captured responsive to the same hand of the user during operative holding of the handle.

44. A method of using a catheter positioned in a hand of a user, the catheter having portions thereof positioned within a cavity, vessel, or tissue

of a human body, the catheter including a handle  
5 configured to be readily held in a hand of a user and  
having a body, a module having an elongate tube  
including at least one lumen extending therethrough  
from a proximal end portion to a distal end portion  
thereof, and a manipulator connected to the body of the  
10 handle and a distal end portion of the elongate tube,  
the method comprising:

connecting a fiberscope to a distal end  
portion of the body of the handle;

15 positioning the fiberscope into the at least  
one lumen of the tube of the module;

connecting the module to the body of the  
handle;

positioning the elongate tube into a cavity,  
vessel, or tissue of a human body;

20 manipulating a portion of the elongate tube  
responsive to a hand of a user holding the handle;

capturing an image of portions of a cavity,  
vessel, or tissue through the fiberscope; and

25 focusing the images captured responsive to  
the same hand of the user during operative holding of  
the handle.

45. A method of detachably connecting a  
catheter having a handle and a detachable module, the  
module including an elongate tube having at least one  
lumen extending therethrough and the handle including  
5 an angled body, the method comprising:

connecting the module to the angled body of  
the handle;

positioning the elongate tube into a cavity,  
vessel, or tissue of a human body;

10 capturing an image of portions of a cavity,  
vessel, or tissue from the tube positioned in a cavity,  
vessel, or tissue; and

15 focusing the images captured responsive to  
the same hand of the user during operative holding of  
the handle.

46. A method as defined by Claim 45, further  
comprising the step of coaxially inserting an  
instrument into a lumen of the elongate tube along a  
substantially straight axis with the other hand of the  
user.

5 47. A method of detachably connecting a  
catheter having a handle and a plurality of detachable  
and disposable modules, each module including an  
elongate tube having at least one lumen extending  
therethrough and the handle including a body, the  
method comprising:

connecting a first module to the body of the  
handle for use in a vessel, cavity, or tissue during a  
medical procedure;

10 disconnecting the first module from the  
handle; and

connecting a second module to the body of the  
handle for use in a vessel, cavity, or tissue during a  
medical procedure.

48. A method as defined in Claim 48, further  
comprising the step of disposing of the first module.

49. A method as defined in Claim 48, further  
comprising the step of sterilizing the handle after the  
step of disconnecting the first module.

**STEERABLE CATHETER HAVING DISPOSABLE MODULE AND  
STERILIZABLE HANDLE AND METHOD OF CONNECTING SAME**

**Abstract Of The Disclosure**

A catheter and methods are provided for inserting at least portions thereof into a vessel, cavity, or tissue of a human body to thereby provide manipulation of a distal portion of the catheter when positioned within a vessel, cavity, or tissue. The catheter preferably has a module which includes an elongate tube having at least one lumen extending from a distal end to a proximal end of the tube, a module interface connected to the proximal end of the tube, and a deflector connected to the tube for deflecting the distal portion of the elongate tube. A handle detachably connects to the module and is configured to be readily held in the hand of a user. The handle has a body which includes a wall positioned in and extending transversely across distal portions of the body. The wall has an outer surface thereof defining an exterior portion of the body and a first cavity formed within the body. Preferably, the body detachably and coextensively connects to the module interface through the outer surface of the wall. A controller is connected to the body and detachably connects to the deflector of the module for responsively controlling the deflector to thereby manipulate distal portions of the elongate tube. The controller and the deflector connect to define a unitary catheter manipulator extending from the first cavity, through the wall, and to the tube for manipulating a distal portion of the catheter when positioned within a vessel, cavity, or tissue.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE: Patent Application of )  
PHILIP JACK SNOKE, et al )  
Serial No.: To Be Assigned ) Examiner: J. Yasko, Jr.  
Filing Date: Concurrent Herewith ) Art Group: 3734  
For: STEERABLE CATHETER HAVING )  
DISPOSABLE MODULE AND )  
STERILIZABLE HANDLE AND )  
METHOD OF CONNECTING SAME )  
\_\_\_\_\_ )

HON. Commission of Patents and Trademarks  
ATTN: Official Draftsman  
Washington, D.C. 20231

TRANSMITTAL OF FORMAL DRAWINGS

Sir:

Please substitute the enclosed revised five(5) sheets of formal drawings, illustrating Figures 1 - 14, in lieu of the informal drawings originally filed in the above-identified patent application.

Respectfully submitted,

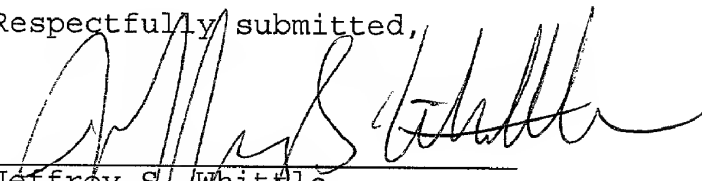
  
\_\_\_\_\_  
Jeffrey S. Whittle  
Reg. No. 36, 382  
Allen, Dyer, Doppelt, Milbrath  
& Gilchrist, P.A.  
P.O. Box 3791  
Orlando, FL 32801-3791  
Telephone: (407) 841-2330  
Attorney for Applicant

Fig. 1.

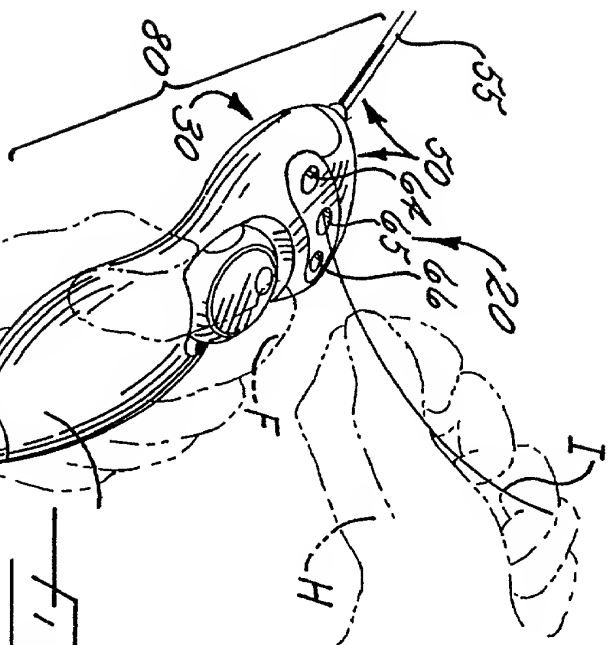
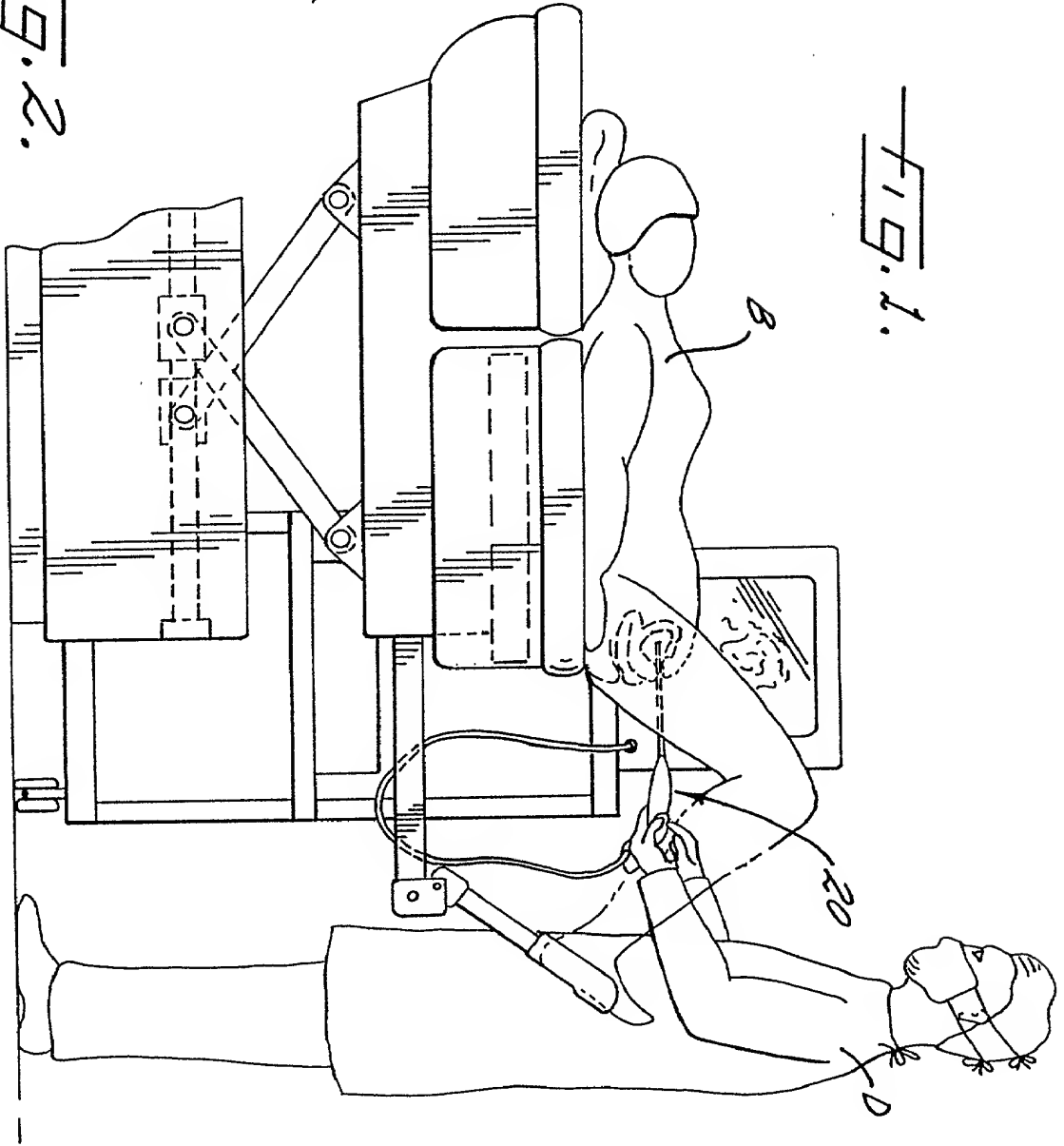
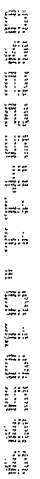
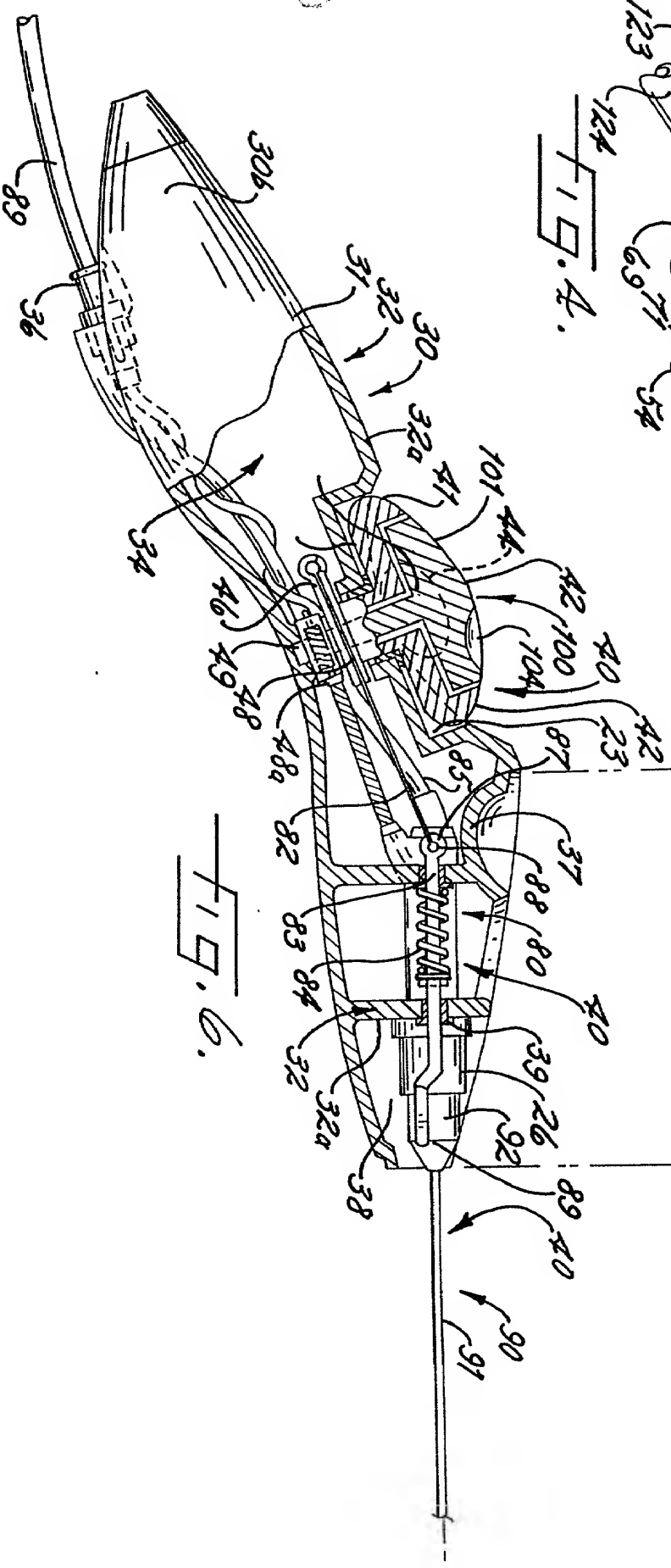
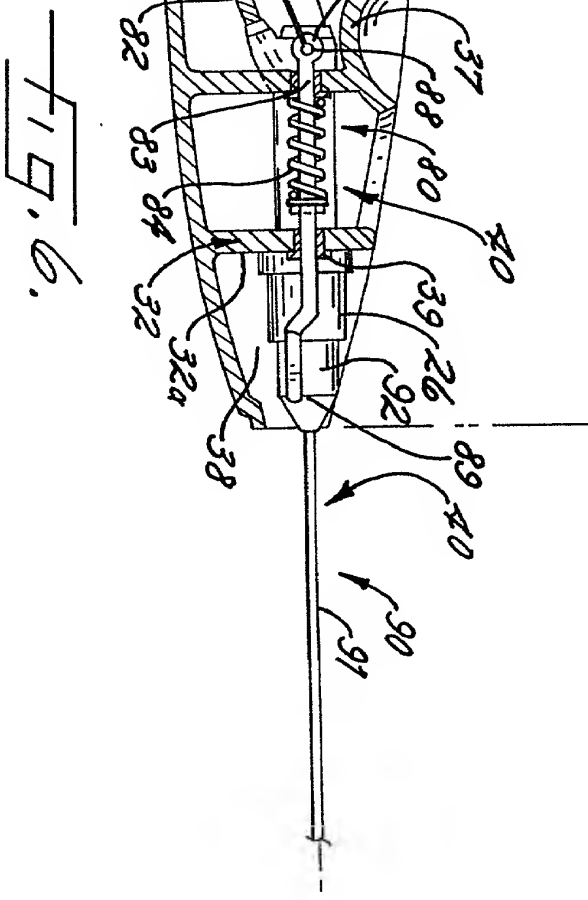
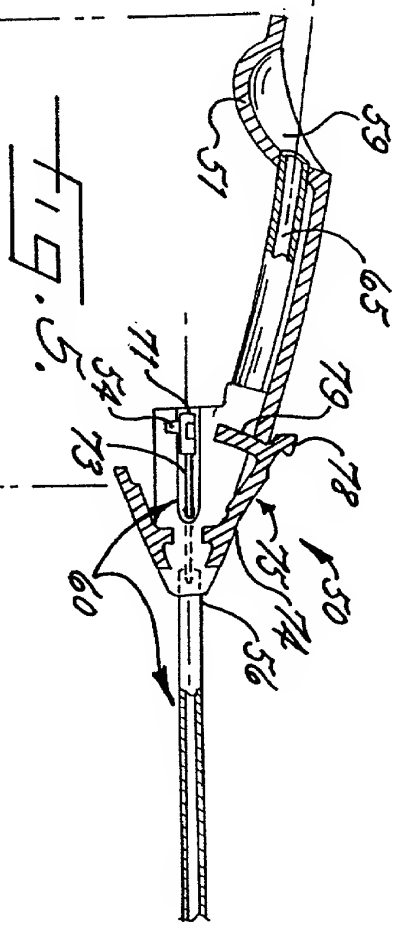
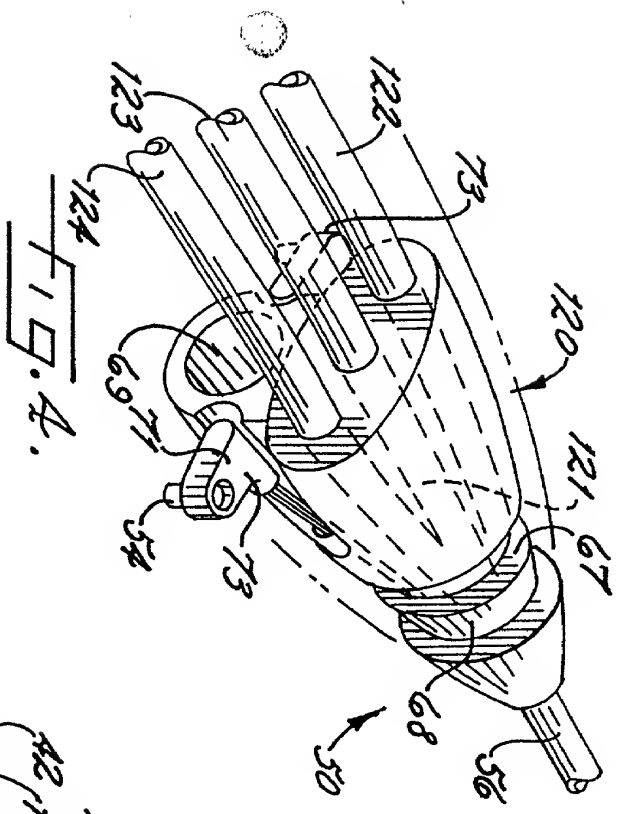


Fig. 2.

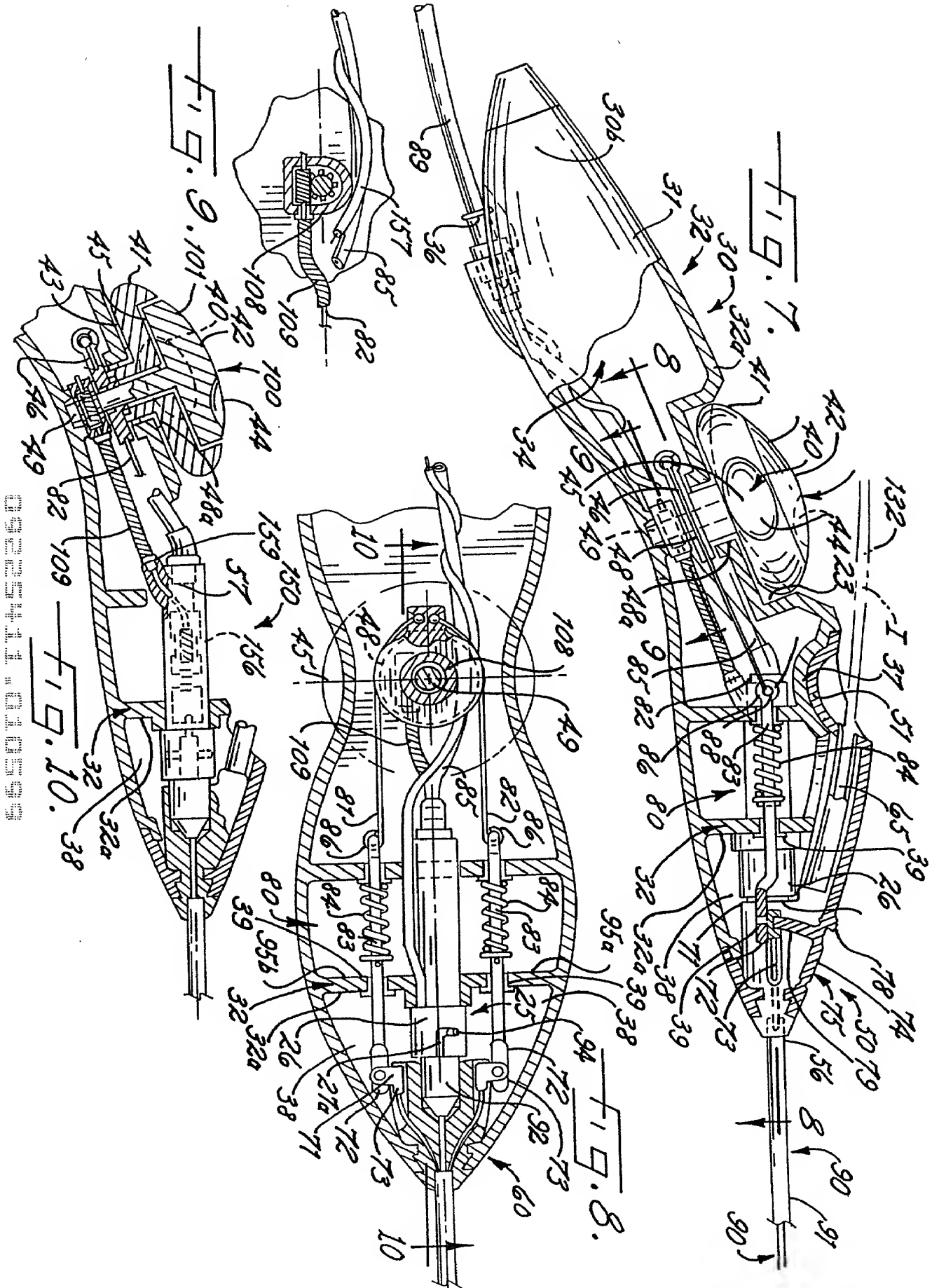
FIG. 1 is a side view of a person using the system. FIG. 2 is a top view of the device.







030625441 010399



U.S. Pat. No. 4,103,999

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent Application of: )  
PHILLIP J. SNOKE ET AL. )  
Serial No. 08/598,804 )  
Filed: February 9, 1996 )  
For: STEERABLE CATHETER HAVING )  
DISPOSABLE MODULE AND )  
STERILIZABLE HANDLE AND )  
METHOD OF CONNECTING SAME )

---

POWER OF ATTORNEY AND REVOCATION OF PRIOR POWERS


Hon. Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Sir:

In the matter of the above-entitled U.S. Patent Application Serial No. 08/598,804 we hereby revoke all powers of attorney heretofore given by us and appoint as our attorneys JEFFREY S. WHITTLE, Reg. No. 36,382; CHRISTOPHER F. REGAN, Registration No. 34,906; HERBERT L. ALLEN, Reg. No. 25,322; CARL M. NAPOLITANO, Reg. No. 37,405; and JACQUELINE E. HARTT, Reg. No. 37,485, of the law firm of Allen, Dyer, Doppelt, Franjola & Milbrath, P.A., 255 South Orange Avenue, Suite 1401, Post Office Box 3791, Orlando, Florida 32802, with full power of substitution, association and revocation, to transact all business in the United States Patent and Trademark Office connected therewith.

The Commissioner of Patents and Trademarks is respectfully requested to forward all communications regarding said U.S. Patent Application Serial No. 08/598,804 to the attention of Jeffrey S. Whittle at the above noted Orlando, Florida address. Direct telephone calls to: Jeffrey S. Whittle at 407/841-2330.

7/3/96  
\_\_\_\_\_  
Date

  
\_\_\_\_\_  
Phillip Jack Snoke  
Vice President of R & D  
Catheter Imaging Systems

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Phillip Jack Snoke et al.

File 4854-13

Serial No.: 08/598,804

Filed: February 9, 1996

For: **STEERABLE CATHETER HAVING DISPOSABLE  
MODULE AND STERILIZABLE HANDLE AND  
METHOD OF CONNECTING SAME**

VERIFIED STATEMENT (DECLARATION)  
CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(f) and 1.27(c)) - SMALL BUSINESS CONCERN

I hereby declare that I am

- ☐ the owner of the small business concern identified below:  
☒ an official of the small business concern empowered to act on behalf of the  
concern identified below:

NAME OF CONCERN: Catheter Imaging Systems, Inc.  
ADDRESS OF CONCERN: 1850 Alma Street  
Atlanta, Georgia 30318

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time, or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either directly or indirectly one concern controls or has the power to control the other or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, captioned **STEERABLE CATHETER HAVING DISPOSABLE MODULE AND STERILIZABLE HANDLE AND METHOD OF CONNECTING SAME** by the inventor(s) Phillip Jack Snoke, Michael J. Mark, and David Scott Rowley described in:

- ☐ the specification filed herewith.  
☒ Application Serial No. 08/598,804; Filed February 9, 1996  
☐ Patent No. \_\_\_\_\_, issued \_\_\_\_\_.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below\* and no

rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e). \*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME: \_\_\_\_\_  
ADDRESS: \_\_\_\_\_  
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

NAME: \_\_\_\_\_  
ADDRESS: \_\_\_\_\_  
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: Jack Phillip Snoke  
TITLE OF PERSON OTHER THAN OWNER: Vice President of Research and Development  
ADDRESS OF PERSON SIGNING: 2785 Arden Road, NW  
Atlanta, GA 30327

SIGNATURE: Phillip Jack Snoke DATE: 2/17/96  
218381

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

Attorney Docket No. 4854-13

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **STEERABLE CATHETER HAVING DISPOSABLE MODULE AND STERILIZABLE HANDLE AND METHOD OF CONNECTING SAME**

the specification of which

(check one)

☐ is attached hereto.

☒ was filed on February 9, 1996 as

Application Serial No. 08/598,804

and was amended on \_\_\_\_\_  
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

English Language Declaration - Continued

Prior Foreign Application(s)

Priority Claimed

<u>(Number)</u>	<u>(Country)</u>	<u>(Day/Month/Year Filed)</u>	[ ]	[ ]
			Yes	No
<u>(Number)</u>	<u>(Country)</u>	<u>(Day/Month/Year Filed)</u>	[ ]	[ ]
			Yes	No
<u>(Number)</u>	<u>Country)</u>	<u>(Day/Month/Year Filed)</u>	[ ]	[ ]
			Yes	No

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below.

(Application Number)

(Filing Date)

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

<u>29/046,932</u>	<u>11/21/95</u>	<u>Pending</u>
(Appln. Serial No.)	(Filing Date)	(Status)
		(patented/pending/aban.)
<u>29/048,898</u>	<u>01/16/96</u>	<u>Pending</u>
(Appln. Serial No.)	(Filing Date)	(Status)
		(patented/pending/aban.)
<u>29/049,058</u>	<u>01/16/96</u>	<u>Pending</u>
(Appln. Serial No.)	(Filing Date)	(Status)
		(patented/pending/aban.)
<u>29/048,899</u>	<u>01/16/96</u>	<u>Pending</u>
(Appln. Serial No.)	(Filing Date)	(Status)
		(patented/pending/aban.)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

English Language Declaration - Continued

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith (list name and registration number).

Philip Summa  
Registration No. 31,573

Jeffrey S. Whittle  
Registration No. 36,382

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Bell, Seltzer, Park & Gibson  
Post Office Drawer 34009  
Charlotte, North Carolina 28234

Direct telephone calls to: Jeffrey S. Whittle  
(704) 331-6000

Full name of (first/sole) inventor: Phillip Jack Snoke

Inventor's  
Signature: Phillip Jack Snoke Date: 3/19/96

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Atlanta, Georgia 30327

Citizenship: United States of America

Post Office Address: 2785 Arden Road, NW  
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Full name of second inventor: Michael J. Mark

Inventor's  
Signature: Michael J. Mark Date: 3/19/96

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Suwanee, GA 30174



English Language Declaration - Continued

Full name of third inventor: David Scott Rowley

Inventor's  
Signature: David Scott Rowley Date: 3/19/96

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